Clinical Operations Workgroup Public Hearing
Draft Transcript
March 28, 2011

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody and welcome to the Standards Committee Clinical Operations Workgroup. This is a Federal Advisory Committee, which means there will be opportunity at the end of the day for the public to make comment. Also, there will be a transcript posted on the ONC Web site. Just a reminder for workgroup members to please identify yourselves when talking, because we are making an audio transcript of this meeting.

Let's go around the table and introduce the members here in the room, beginning on my left with Chris Brancato.

Chris Brancato – Deloitte – Manager, Health Information Technology
Chris Brancato, Deloitte Consulting, contractor to ONC.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
John Derr, Golden Living, representing long term and post-acute care.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Stan Huff with Intermountain Healthcare and University of Utah at Salt Lake.

Judy Murphy – Aurora Health Care – Vice President of Applications
Judy Murphy from Aurora HealthCare in Milwaukee, Wisconsin.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Chris Chute, Mayo Clinic.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Jamie Ferguson, Kaiser Permanente.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Elizabeth Johnson, Tenet Healthcare.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Wes Rishel, Gartner.

Kevin Brady – NIST – Principal Investigator, IIEDM
Kevin Brady, NIST.

Jay Crowley – FDA – Senior Advisor
Jay Crowley with the Food and Drug Administration.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Terrie Reed, Food and Drug Administration.

Judy Sparrow – Office of the National Coordinator – Executive Director
We do have a number of members on the telephone. Joyce Sensmeier, are you there?

Joyce Sensmeier – HIMSS – VP of Informatics
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
Don Bechtel?

Don Bechtel – Siemens Medical – IT Architect, Standards & Regulatory Mgr.
Yes, I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Dixie Baker?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Anyone else on the telephone? Okay, with that I'll turn it over to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I want to welcome everyone to this one-day hearing on barriers and enablers for device interoperability in healthcare. We're here to seek a greater understanding on this set of issues for the Health IT Standards Committee. The scope of the Health IT Standards Committee and the Clinical Operations Workgroup in particular, is to recommend standards for electronic health records and other clinical operations technology to achieve the goals of ARRA (the Recovery Act) to aid adoption of health IT. Beyond that, now with the passage of the Affordable Care Act the scope has been expanded to the adoption of health IT and health IT promotion in that broader context.

The idea for this hearing grew out of some previous testimony and discussion in the Health IT Standards Committee indicating that providers who were seeking meaningful use stage one incentives were experiencing difficulty interfacing vital signs information automatically from devices and also they were not finding easy and convenient ways and places to store such information in the EHRs. So we had a variety of discussions, and the idea for this hearing matured so the discussions broadened into the scope of questions and the panel discussions that we have here today. So while we do need to keep a focus in terms of the workgroup and committee recommendations on meaningful use and implementation of the health IT implementation provisions of the Recovery Act and the Affordable Care Act, this broader discussion may also assist ONC in its role as a coordinator across multiple federal departments and agencies.

We have truly a stellar set of panelists representing a variety of stakeholder views and different interests here today, and expect to hear, and if you reviewed the written testimony that was published on the ONC Web site and published here today, you can see we have quite a variety of different opinions presented here. So I'm really looking forward to the discussion. Does anyone on the committee have any further opening comments before we turn it over to the first panel? The order of business here is each panelist will speak for a few minutes. We'll go in order on the panels and then we'll just open it up for workgroup committee discussion.

I guess then without any further opening comments I'd like to turn it over and introduce our first panel. We have Rob Havasy from the Center for Connected Health, we have Courtney Rees Lyles from Group Health Cooperative, and Robert Jarrin from Continua Health Alliance. Rob, I think it's over to you first.

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
Thank you very much. On behalf of the Center for Connected Health, I would like to thank the committee for the opportunity to speak with you today. The Center for Connected Health, as you may know, is part of the Partners Healthcare System in Boston, Massachusetts. In addition to conducting research in the connected health area, we find our mission is to find new ways to leverage technology to deliver care outside of the traditional setting, which means that we put real medical devices into the hands of real patients every single day. As the operations manager for the center, it's the job of my team and I to troubleshoot these devices and to try and make them work the best that we can, and we are finding this to be a very difficult challenge.

Before I get too deep into that I would like to say something about the word "patient," and this is a panel about the consumer and patient experience, I think consumers and patients are different and the differences are important. When we use the word "consumer" in my mind we denote someone who can exercise choice in the marketplace, someone who can look at a range of options and decide to purchase or use an option that best suits their needs. Consumer also denotes to me something that companies can segment and market and target very specifically.

In the healthcare world, we deal with patients. Patients are surely a subset of consumers, but there are some key differences. For instance, if we look at research from the Pew Internet & American Life Project we know that patients living with a chronic disease, one or more chronic diseases are less connected to the Internet than consumers in general. They use technology, cell phones, less than consumers in general. More importantly, by definition patients are under the care of a healthcare provider and usually in conjunction with some sort of payer, and they take the recommendations of their providers and their payers for technology based on what their providers can use and integrate with their own systems and what their insurers and payers will reimburse. Therefore, their choices are limited.

In healthcare, we strive for the broadest possible reach and we take the people who come through our doors. We don't get to segment and target our markets as much as companies might. When we find a solution that's effective, we seek to deploy it as broadly as possible. If I've learned one thing from the patients I've worked with over the last few years, it's that most of them don't care how the devices we give them work. They just care that the devices we give them work when they take them home.

In the last few years, I have personally deployed hundreds of devices to hundreds of patients in groups in one-on-one sessions. My help desk and I have fielded probably by now thousands of calls on how those devices are or are not working. The questions that patients have asked me during these deployments range from tragic to comic, but I can tell you that not once has a patient asked me what particular standard a device supports. I can tell you that I've never been asked whether data is transmitted under CCR, CCD, X12, HL-7 formats. What I get asked all the time is if I take this home and plug it in it's just going to work, right? Or, can I share my blood pressure with Dr. So-and-So? So the patients clearly have a vested interest in the discussions we're having here today. I have found very little interest in the mechanisms that are going to make them work. They care that the devices we give them work, not necessarily how.

One of the problems we're facing right now is that patients have access to a broad array of communications technologies. Statistics, again, from the Pew Foundation, from the FCC, from the wireless industry association tell us that only 50% of Americans, for example, still have a traditional landline telephone. The other half have either gone cellular only, or are using some form of new digital service. If you incorporate the possible array of computers and broadband networking or other network technologies that patients may have in their homes, the landscape becomes very complex, and making devices work in this complex landscape is an increasingly difficult challenge.

One of the constant struggles we have at the center is to get patients to take a device for a particular technology and become active in our programs. The number one reason that they do not become active is because we cannot make the devices work with their particular combination of communications technologies. Illness places a particular burden and a considerable burden on patients and their families. In many cases, there are simple technical solutions to the problems that we encounter. But implementing them is just one more challenge that an ill patient does not need. So to be clear, when I look for compatibility I'm not looking for the next new device or the next new technology to really make this better. I think we're already under-utilizing many of the technologies that we have for home monitoring. For instance, wireless technologies certainly show promise, we have wireless devices incorporated into our programs right now, but even in Massachusetts, I cannot guarantee that a patient is going to go home and find they have sufficient coverage by the right carrier and the right signal in their home. I imagine this is a much greater challenge in a more rural area than Boston.

I recently had the privilege of speaking in Brussels, where Dr. George Crooks, who's the head of the Scottish National Telemedicine Center, said to the audience, "If we could just deploy the devices we had five years ago we'd all be better off." I really couldn't agree with him more. So standards I think can address this and can help this situation. But recognizing the difference between patients and consumers, that the patients' choice is often very limited and that they are often under extreme burdens from their illnesses, we can write standards that drive programs towards broad compatibility and broad deployability, rather than many devices targeted at small niche markets. I think if we can do that we can give patients their devices that will just work when they take them home and plug them in. Thank you very much.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Courtney?

Courtney Rees Lyles – Univ. of Washington – Group Health Research Institute
Good morning. My name is Courtney Lyles and I'm a post-doctoral fellow at the University of Washington, where I work with the Group Health Research Institute on research for improving care for chronic illness. Thank you for the opportunity to share our research experience, especially as it relates to patients managing their chronic illness with home monitoring. Over the past decade, our consortium has conducted several trials of diabetes care management, with patients tracking their blood glucoses at home through both the Web and mobile phone-based monitoring. Our work has found some positive associations between home monitoring in collaboration with the provider and improved diabetes outcomes. I'll describe just a few examples.

In a randomized control trial, we found that home glucose monitoring coupled with secure electronic communication with providers improved glycemic control by about a 0.7% decrease in hemoglobin A1C among patients with type 2 diabetes. In qualitative assessments with patients and their experiences using these systems, patients found uploading their blood glucoses and the feedback they received about them extremely valuable.

Our most recent work expanded these trials to allow patients to wirelessly upload glucose levels through Bluetooth-enabled glucose meters and smartphones. This let patients receive ongoing care management even when they weren't sitting down at their personal computer. Again, patients were enthusiastic about wirelessly uploading, particularly as part of the shared plan with their provider, but due to resource constraints and lack of interoperability standards between the devices, we built our system for one cell phone platform and one glucose meter only. Most patients, therefore, had to switch to at least using one unfamiliar device, and that frustrated them. Patients strongly preferred using devices with which they were already comfortable. When patients disliked the glucose meter or the smartphone we provided, it provided barriers against their self-management, the opposite of our intent. That's why we think in order to meet the needs of patients it's essential to establish standards and meet patients' expectations about interoperability standards, not only between electronic health records and devices, but also between devices themselves.

Patients should have the flexibility to choose which devices they use as one-step towards adoption of the technology and co-management of their healthcare. In addition, device interoperability enables a seamless workflow between a patient's day-to-day management of their illness, and the provider's guidance for long-term outcomes.

We appreciate the work of organizations developing promoting standards for home monitoring interoperability, which would lead to improvements in continuity of care. Without this flexibility in patient choice patients may not adopt new technology and lack of standards could lead to a fragmentation in the care experience and potentially disrupt existing patient-provider relationships. Patients are increasingly engaging in healthcare through electronic health records. At Group Health Cooperative in Seattle 64% of the approximately 300,000 adult patients use an electronic health record that is shared with their provider, and patients with ongoing conditions such as diabetes and depression are much more likely to use these services in our system. Still, we lack the standards that will let our patients connect their online care to many of their personal medical devices, such as glucose meters.

Our experience also aligns well with the currently proposed meaningful use criteria in stage three, including offering electronic self-management tools to patients with high priority conditions, offering the capability to upload and incorporate patient-generated data into the electronic health record and clinician workflow, and having the ability of electronic health records to exchange data with personal health records. We believe that these criteria are appropriately in stage three rather than stage two to give industry and researchers time to further tackle some of these usability challenges in home monitoring systems. Further, we support the additional recommendations for reporting patient preferences for communication medium and offering patients the capability to report their experience of care, including experiences related to home monitoring.

In the future, home monitoring holds promise for improving healthcare outcomes and care satisfaction for patients with chronic disease. Patients' needs and preferences must be kept at the forefront of these discussions to ensure that the systems promote chronic self-management as part of everyday life. Without incorporating the quality of the patient experience into the processes for developing standards and subsequently improving them, we risk weakening the potential to reduce chronic illness burden. I hope our experience can provide some insight into this discussion. Thank you very much.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you, Courtney. Now we'll move on to Robert.

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
Thank you. Good morning, Chairman Ferguson and members of the HIT Standards Committee Clinical Operations Workgroup. My name is Robert Jarrin and I serve as Co-Chair of the Continua Health Alliance US Policy Workgroup. I am also a Senior Director of Government Affairs for Qualcomm Incorporated. The Continua Health Alliance is a non-profit, open industry coalition of healthcare and technology companies, patient organizations, and associations that are joined to collaborate and improve upon the quality of personal healthcare. On behalf of the 240 members of Continua, I would like to thank you for the opportunity to present testimony on the important issue of device interoperability.

Whether telehealth, mHealth, remote monitoring or electronic health records, Continua strongly believes they all make up the foundational elements of health information technology. HIT is not limited to the mere exchange of electronic health records among providers, but rather encompasses a broader, richer ecosystem that begins with how raw diagnostic data is captured from a patient and then derived. Patient data should begin when an interoperable medical device, a sensor or other HIT product obtains a person's physiological statistics. That data should then be transmitted through a number of common specifications to ultimately populate a patient's PHR, EHR or on to an HIE. Those rich elements of information are vital throughout the continuum of care that will someday be further enhanced by a nationwide health information network. From the onset of the definition of meaningful use and the subsequent Medicare and Medicaid incentive program, Continua's members have maintained that capturing a patient's data is just as vital as the EHR which that data should someday ultimately help form. We feel that in order to truly achieve the goals described by the ONC, which were to enable a significant and measurable improvement in population health through a transformed healthcare delivery system, that greater emphasis needs to be placed on how patient data is captured, derived and transmitted via interoperable devices.

The objective for today's hearing is titled, "Identifying Barriers and Enablers for Device Interoperability." Thus, we urge the Clinical Operations Workgroup to consider the following barriers and enablers. The ONC should accelerate its proposed stage three objectives and seek to include engaging patients and families in their own care as immediate objectives. Both the HIT Policy and Standards Committees should address this core concept that is currently not being considered until possibly stage three of meaningful use, if at all. The incentive program needs to be expanded to include electronic self-management tools for patients with high priority health conditions while offering the capability to upload and incorporate patient-generated data such as electronically collected patient survey data, biometric home monitoring data, patient suggestions of corrections to EHRs and clinician workflow.

Another well-known barrier to interoperable devices is the criteria for allowing Medicare reimbursement for telehealth and telemedicine. Simply stated, reimbursement issues have stifled the adoption of some health information technologies because CMS continues to define telehealth in narrow and outdated ways. Reimbursement should be permitted in all settings where there are clear technological benefits to patients, providers and insurers. Healthcare management should not be limited to only live encounters, where store-and-forward technologies are perfectly capable of augmenting reliable, consistent, diagnostic care. If a Medicare benefit plan covers a service, then that plan should also cover the same service when it is performed remotely.

Continua is dedicated to establishing a system of interoperable personal connected health solutions. Continua is not a standards setting body, rather the Alliance selects existing commercially available standards and within those parameters adds definitions or refinements. Standards chosen by Continua include USB, Bluetooth and ZigBee. The process begins by choosing real world healthcare use cases. Member companies then select the best industry standards, hold a ballot process to finalize specifications and finally, publish guidelines for the membership. The results of this process are evident in the devices that have achieved Continua certification. The majority are medical devices that can be used in both clinical and home settings, devices like pulse oximeters, blood glucose readers, blood pressure monitors, medical grade weight scales, pedometers, laptop computers, medical gateway platforms, and mobile phones.

In a system well designed for improving health, people with chronic diseases or failing health should be able to transmit their vital signs seamlessly, from anywhere, at any time, to anyone, and most importantly to their healthcare professionals. Regrettably, that is not really the norm, it is the exception. There are many barriers to adoption for these technologies, however, there are many enablers that the federal government, starting with this Workgroup, can help advance. Continua hopes this Workgroup's interest in patient and consumer device interoperability will continue and we are here to pledge our support to make meaningful progress towards a transformed healthcare delivery system.

With that, I respectfully conclude my prepared remarks and welcome any questions you may have. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you all very much. I'm going to take the prerogative to ask the first question, and then I see Liz's card up first. My question is really for Rob and Courtney, from your experience in running these systems in the field. From the consumer's perspective, I heard a variety of different barriers, and I'm wondering, what are the greatest barriers? There were barriers about establishing initial communications, there was reliability of communications after the program was underway, but there was also lack of consumer choice of which devices could be used to establish interoperability, so what were the biggest barriers from the consumer perspective?

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
Courtney identified the first one, and I'll try and give them in a rough order. Patients normally have a set routine of care. We offer a diabetes management program similar to the one Courtney described, and she is absolutely correct, patients have a glucometer and if our program's not compatible with that glucometer they don't want to switch. Beyond that, there are insurance or other concerns. Diabetes is a classic example again. Patients often have a formulary that says they can use these glucometers and they get this many strips, and even if they're willing to change technologies to accommodate a program they may have to wait the 60 or 90 days that they already have a supply of glucose testing strips. The initial choice getting them out of their routine and into a new routine can be very difficult. I'd prefer not to change their care routine, honestly, if I had a device that was universally compatible.

The second problem is just that once we get a patient to agree to be part of a program, it's often getting the technology to work that is a hurdle. Again, Courtney mentioned some things that resonate with me. If we use a program that uses a smartphone there are so many different models, so many different carriers, it's very difficult to build something that will work across programs. In our world in Boston we have a very competitive communications market. Customers can have three different digital phone providers, they

can have two different analog phone providers, and they can have a variety of network providers at home, broadband or otherwise. Just finding the right combination of things that will work so that they do not have to reconfigure their home communications environment is very difficult.

Courtney Rees Lyles – Univ. of Washington – Group Health Research Institute
Yes, I would like to echo all of those points. Ours is a little bit different in the sense that we didn't go into peoples' homes and assess what existing systems they were using. We were forced to use the existing smartphone platform and Bluetooth-enabled OneTouch meters that we were providing during the trial. I would say that the biggest challenge was I think patients didn't anticipate the number of barriers that they would have in using a new device, so they were very engaged in the uploading and home monitoring and the engagement with their provider in particular about their glucose monitoring. But when the barriers emerged it really put up a huge wall to move forward in the process, and even working through some of those problems several of the patients actually chose not to participate any further because they did not like the smartphone or the meter that we provided in the trial. And I would say that's a pretty large barrier if they refuse to participate any longer.

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
If I can add one more comment. A few years ago in the forward to a Pew research forum they said, where I took some of my information, that patients already have considerable burdens in their lives and sometimes even a simple technical solution is just one more burden they don't need.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. I saw Liz and then Chris and then Wes.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Thank you for your testimony. It's very compelling to see the empathy that you have for our patients and what is needed. It's interesting, I didn't hear you, and we've heard in other hearings that patients were concerned about the security of their information or their privacy, and that wasn't identified in what you said. I think your points are extremely well taken, but what are you hearing from patients about their concerns related to their information going to the wrong place or whatever? They're shaking their heads.

Courtney Rees Lyles – Univ. of Washington – Group Health Research Institute
In our qualitative follow up, we actually ask that specifically from all of our patients participating in the trial, and that was actually not a very large concern among patients in our trial. I would like to say that as a caveat, people who agreed to participate in a trial like this perhaps have lower amounts of concerns about the security of their information online, but that was not a barrier and at no point during the trial did that come up as voiced from any of our participants.

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
In focus groups that we hold with our patients, I guess I could best sum it up as they trusted people in the white coats regardless of what technology is involved. We had one program where we integrated a personal health record from outside of our system, and there were some more concerns raised there. So I think patients in particular trust the medical establishment, they trust maybe corporations a little bit less, and they trust some other people even less than that.

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
If I can chime in on this one, I've listened to a number of presentations done by the Office of Civil Rights, specifically those representatives that are overseeing HIPAA and the changes to HIPAA through HITECH. Interestingly, in those presentations you will notice that technical and really the safeguards that are in place for technological solutions aren't the ones that are breached. It's usually more done because someone leaves something somewhere that they shouldn't have, for example, tapes or laptops or smartphones that are not encrypted with certain information about patient data. That's what ends up becoming breached. It's not necessarily a technical issue.

I do offer the following. In the mobile banking world hundreds of millions of dollars, if not billions of dollars, are transacted by the minute over smartphones and other likewise portable and mobile devices,

and those haven't been hacked into. I'm not saying that they're not going to. However, if someone's going to be pursuing information from me, for example, I would be more worried about that information than my blood pressure or my glucose readings. It's just an analogy that I'm trying to make, but I'm offering it from our perspective that it really seems to be more breach notifications or breaches done by people inside the system or those that are unauthorized to obtain that information, that's where that's happening.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great, thanks. Chris?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I think I have a question for each of you. Robert Havasy, if I could begin with you, I appreciate the careful distinction that you made between the consumer and the patient, but my question is, who should be the determinant of standards and interoperability? You've asserted that it shouldn't be the patient that decides whether it's HL-7 or X12 or whatever permutation of standards questions, and I can see that to some extent, but consumers made choices between Blu-ray and HD DVD, VHS and Beta, we can go down the list of competing standards that were ultimately consumer choice. In the context of your distinction between patient and consumer, who should be making those choices about which standards actually provide satisfactory interoperability and functionality in the kind of plug-and-play modality you characterized?

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
That's a great question. I think there's a place for several players. As technology progresses, there are already a number of agencies which are putting standards in place. We have the FCC for communication standards, we have the FDA for medical device standards, and there's absolutely a place for those to continue and be increased. I wish patients would step forward and, say, form a market and drive this discussion. But it's been my experience that they're just not interested, and even if we ask the question, if we gave you this device versus this device. I'll give you the experience again of my father-in-law, who was probably one of the last polio victims in the United States who contracted back in the '30s. One day when my mother-in-law asked him what necktie he wanted to wear he looked at her and said, honey, I'm just trying to stay alive. So as much as I wish patients would step forward and the market might decide, I don't think they will.

To answer your question, I think it's smart people getting into a room like this. I think it's Continua, who the Center for Connected Health is a founding member of. I think it's the studies that we're doing and the focus groups that we hold afterwards that will try and drive this. Those patients who make it past the gateway, those patients who become active, patients from the Society for Participatory Medicine, for example, patients who you'll find on e-patients.net who have made it beyond the hurdles of technology and are now truly engaged in their care, I think they should have a voice at the table. I think they will demand a voice at the table and begin to push this from the patient perspective.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
My question for Courtney is, you made, I think, the apt observation that patients prefer to have their own devices and it would be cool if we had interoperability that would work in whatever device they happen to have or happen to use because of the barriers that changing devices pose, and I certainly buy that logic. However, if I could turn that into a question, you're really talking about a meta-standard—if I can use that term—that would operate against a suite of infrastructures and devices and capability. Yet, virtually all the standards in that space, the small portable device space, have been manufacturer driven, so it really begs, who would make the meta-standard to achieve the kind of interoperability you have? Are you in a position to give that a whirl?

Courtney Rees Lyles – Univ. of Washington – Group Health Research Institute
I don't think I can speak to that, except to the extent that I think groups like this are great for exploring these options and to establish standards. From the patient perspective or from our trials, I would say that one of the questions was wave a magic wand and what would you wish for, and I think from a patient perspective what they would say was they would not like to change any devices and they would like that

plug-and-play feature. Whether or not that's a possibility or a reality is yet to be determined, but I guess that's the way I would state that question. In terms of who develops meta-standards and what that would be I think that's a little bit further down the road in terms of our research and what we're dealing with.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Robert Jarrin, excellent presentation. I learned a lot. I hadn't appreciated what Continua was, I'm embarrassed to say, but it sounds as though you are actually creating, if you will, a de facto standards evaluation and implementation process. In the context of the two earlier responses to my questions of who should decide what the standards are and who should develop the meta-standards, what role could Continua play in those processes?

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
I believe Continua can play a liaison role between the different parts of the industry and the different industries that are involved in trying to tackle the issue of healthcare. Continua really approaches everything from a member perspective. We do not create standards, and I really want to stress that. Standards take a long time to create; they're very difficult. It takes a lot of competing interests to try to come into thinking in one set way and it often leaves out very important aspects that unfortunately get left by the side. Continua has really taken a top-down approach of let's choose those standards that are existing which are commercially available. Bluetooth is a great example. Bluetooth is a wonderful interface. However, most of the membership felt that it may have been a little weak in its security to deal effectively with health data.

So what Continua did was they got together, they helped define something called a Bluetooth health data profile, which really strengthened it a little more at the handoff component of it, and in doing so strengthened Bluetooth. So now that Continua members do use Bluetooth it's a little stronger. But again the idea is that working as a membership as a number of different stakeholders within this whole area, because there are very many different industries—you've got technology companies. You've got telecommunication companies. You even have consumer patient groups like the American Heart Association, the Center for Aging, the CAST, ... Center for Aging Services Technologies, and the Care Continuum Alliance, they all take part in this. I really do think that this is something that's going to be driven by the industry, by companies, by technology. Technology moves unfortunately and fortunately at the speed of light, government does not. It's often more reactionary than proactive but I think that the ONC has been a real leader in this area by making sure that everyone is speaking to each other and you're asking the right questions. I just hope that they keep asking the right questions and keep being involved.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I want to spend some more time on Continua, and I'll hold that to the end. I'll come back to you, Robert. As a bit of background, the Standards Committee has been grappling with the tradeoff between complexity and widespread adoptability of standards and developed some principles early on that effectively said find something that works and adopt it. Find something that's being used that's been through this. Unfortunately, we seldom have had the opportunity to actually live up to that motto. The first question I have, Courtney and Robert started out with considering the testimony limitations ... a reasonable amount of information on the clinical or economic benefits of home monitoring. I wonder, are there studies that define that better that you could perhaps provide us after the meeting references to that would be useful in justifying whatever effort or change in priorities or anything might go on. I think it would be helpful to get those available to the public through the Standards Committee basis. Do you have such studies?

Courtney Rees Lyles – Univ. of Washington – Group Health Research Institute
Yes, our group has produced several studies. They're included with our written testimony. It didn't make it into this packet here, but it's available online, including the randomized control trial where we looked at hemoglobin A1C as a primary outcome and found some significant improvements. We also have several

qualitative assessments that I spoke of about the positive patient engagement outcomes and patient perceptions of these systems, which are also on the positive side. Patients really did enjoy collaborating with their provider, and I think I wanted to stress that one more time that the collaboration piece with the provider was a really critical component of the success of our trials. The technology without a link to a person on the other side of it or without any feedback from the provider was not viewed as very successful. But in the qualitative assessments when they had a shared plan with their provider there was a lot of positive feedback about the trends that they received as well as their increased health awareness, and there are four studies in particular that are in the written testimony ....

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Robert?

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
I second that, absolutely, and the papers that have been included in Courtney's testimony are very valuable. We have a few in publication right now that are working their way through the system on both congestive heart failure and diabetes and some others, and I'd be happy to include references to those. Yes, there are some others that we look to once in a while.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
You both have I think been very helpful in stressing that the technology is at best an enabler to what is in effect a collaboration between the care team and the patient, and not a very good enabler at this point. In those care teams are you finding you're using more multi-license care teams as opposed to just physicians?

Courtney Rees Lyles – Univ. of Washington – Group Health Research Institute
Yes, we are. Both in our trials at the University of Washington and at Group Health Cooperative we try to design our trials with the chronic care model in mind, which is the entire care team working with patients. The dedicated diabetes case manager who was involved in several of our trials was a nurse practitioner and specializing in diabetes care specifically.

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
Without question, these are multi-disciplinary care teams. Our most successful program to date has probably been in hypertension. That involves everything from dieticians and educators through the nurses who look at the data and nurse practitioners who work with the patients, and group sessions where the patients actually come into a community practice once every week for four weeks and learn, in addition to using the technology, how to read labels and alter their diet and those things. So, absolutely multiple disciplinary approaches are the way to go.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Given our sensitivity to wanting to find something that works and follow it, have you seen any glimmers of hope on the horizon? I know there was Microsoft Connection Center for a while, there have been other PHR in the center kind of arrangements, have you seen anything really that has been effective so far even if you didn't have the option to include that in your own trial?

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
I don't think I've seen anything that puts it all together. I've seen devices that gather data that we can then import into our own electronic health record systems, but lack the component of sharing that back through, say, a personal health record. I've seen some promising work in personal health records, but their compatibility with devices and the data they can intake is lacking. So, no, I've not seen anything that brings both of those components together yet.

Courtney Rees Lyles – Univ. of Washington – Group Health Research Institute
Yes, I would also echo that. Even though the electronic medical record systems, both at the university and Group Health, are very comprehensive, they're lacking in the medical device arena and the ability to add that data into the electronic health record itself and to then generate those trends and that feedback that patients really valued in our trials.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Robert, Continua was formed about 2007, is that right, 2008?

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
I believe it was five years ago, or four years ago.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Along the lines of find something that works and then adopt it, can you point us to of successful deployment of Continua-based products in a program such as Courtney and Robert have been describing?

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
Absolutely. One example that I wanted to use today was an example of a trucker, his name is David Jesse. He joined the disease management program at the Cleveland Clinic, which was working with one of our members, the name of the company is MedApps, and they have what is essentially a wireless hub that can transmit information anywhere. What he has linked to that are certain Continua certified products, including a blood pressure cuff monitor and others. This trucker, David Jesse, is one of the examples that was used in the press because it helped lower his high blood pressure, etc., but it was part of a greater effort done by the Cleveland Clinic with some very promising outcomes.

A second example that I wanted to use was a gentleman by the name of Dennis Ward. He's a patient of Providence Medical Group in Portland, Oregon. He has diabetes, high blood pressure, takes 14 different medications, but using one of our other members, the Intel Health Guide, to help measure glucose and other things through periphery devices that report into the health hub has also showed a lot of promise. This is part of a greater effort. I'm using these people as just examples of real life human beings that use these things.

Another is an example locally, Dolores Smith, who took part of a Qualcomm funded study here in D.C. which was completed just about a month ago using smartphones that were enabled with an application called "The Pill Phone." Dolores has high blood pressure, congestive heart failure, and the idea behind that was to use it for medication adherence. The study was conducted for about six months, and again showed very promising results. All of these used peripheral devices, or a device itself, to take information from the patient, which the patient can then transmit back seamlessly without them having to do any of the heavy lifting.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Let me interrupt for a second. The first names of the patients is a great means of communicating for presidents and secretaries of Health and Human Services, but we're a little more nerdy here. What I'd like to know is the names of programs that were based on deploying instruments that were based on Continua standards that have demonstrated something approaching the level of success that Robert and Courtney described.

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
Sure. I would say again that the Intel Health Guide program, which was actually done through Providence Medical Group using a certified device or a device that used certified devices, MedApps, working through the Cleveland Clinic. It's a Cleveland Clinic study again using peripheral devices that are Continua certified, which reported information back into that study, we can provide you with information and details of those studies.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, I think we'd be interested in seeing—

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
There are other Continua Health Alliance members that have done equal work in the field. I'm sure that they use some devices, maybe not all the devices that Continua has offered., but they can also report

back in. For example, Bausch has been very much involved with the CMS, doing a number of pilot studies. I believe that they use some of those devices as well.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I would be delighted to see studies that showed effectiveness, that showed that the basic thing worked, and demonstrated a level of patient acceptance that is the key thing that Courtney and Robert had described in their communication. Thank you. That was very interesting.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. I think Chris Brancato was next.

Chris Brancato – Deloitte – Manager, Health Information Technology
First, thanks for coming. Thank God you got a sunny day in Washington, D.C. I have a couple of questions. My colleague, Liz, talked about the privacy and security standards, so I want to hit another area, the pointy tip of healthcare delivery using these devices. What are the challenges you're having in identifying the devices to your applications and certainly identifying the patients to those devices? So if you could elaborate a little bit on those challenges you're having, if you're having any.

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
I'll take that and begin. The challenge is not so much the technological challenge, but there are certain barriers to the adoption, not to sound cliché-ish. We find that you either have institutions and hospitals and doctors that are really wedded to technology and very much interested to proactively engage in adopting these technologies using them in their practice, teaching their patients how to use them, and working with them. Then you have the rest of America, which really is lagging in that department. There are many obstacles in the sense of teaching and engaging patients because the institutions themselves, or the doctors themselves aren't really interested in it, they're very much rooted in traditional technologies that are easy, that they use, not even thinking that well, this information can be reported back to me without having the patient come in. My mother is a cancer patient, and I can't tell you how many times I've had to bring her in just to get a blood test or a blood pressure reading or a pulse oximetry reading, etc. It takes time away from my job. It takes time away from her life for things that can be done at home.

So the barriers aren't really the technological barriers or identifying which use cases. That's one of the reasons why Continua is so prominently used as a use case scenario, we go through so many healthcare industry use cases to make sure that we really are identifying what's going to make a difference in peoples' lives from a healthcare perspective, taking those use cases in, and then we try to channel the best technologies. It's very important to say that when I talk about a technology like Bluetooth, ZigBee, or USB, it's not just a technology, it's something that doesn't exist, it's a membership organization that represents Bluetooth, which is involved in Continua, and they're bringing their perspective of how they can solve a problem or try to help augment existing barriers. So really from a technical perspective many things can get done, but identifying it, it really takes an entire membership to really key in on it. Then once you do understand try to go into a certain area, develop a use case, and then each company has to literally go out and test design product cycle, bring it to the FDA for their clearances and classifications and approvals, and then the product comes out to market.

But once the product comes out to market, unfortunately, there isn't really a very strong market that has been developed where doctors immediately say, yes, this is something that we want to use, or healthcare facilities immediately gravitate towards this stuff. Which is one of the reasons why in my comments I wanted to make sure that people understand the notion that when we're incentivizing meaningful use, incentivizing the adoption of EHRs. I think a lot of the healthcare industry focuses myopically just on the EHR and that exchange of EHR without thinking, hey, I've got this whole wall behind me of manila folders where all of my clinicians and support staff have written in things on their hands and little pieces of paper and stuck it into huge files. What happens if that file gets lost, what happens if they transpose your information for mine. That's a continuation of what's really been going on until we really proactively try to make them understand that if we incentivize you for adopting these technologies, then that will change as well and there will be a greater focus by those healthcare professionals to really focus on these technologies. I hope that answered your question.

Chris Brancato – Deloitte – Manager, Health Information Technology
I do want to put a clearer lens on this, so using the example use case, I take a patient to the OR and I put a pacer in them. Part of that operative procedure is to take the medical device number and to marry that to the identifier to that patient. You don't have the luxury of having that one-on-one attribution right there on the operating table. I'm curious to see of the rest of you who are implementing those devices who's capturing that data, how's it stored, how's it available to other users of that data.

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
I think there were two parts to your question. The first one is I will say that identifying technologies and devices has become infinitely easier since ARRA and since the industry smells money, I'll put it that way. Two years ago, there was no such thing as a booth at the Consumer Electronic Show for Healthcare and now it's a quarter of one of the floors, so identifying the technologies is getting easier.

As far as how do we handle these things to turn them into programs, how do we handle this data, at Partners we had to build our own systems from the ground up? I would estimate that over the last five years we've probably put close to a million dollars into a system to essentially put other parts of our healthcare system out of business, which is the paradox, right? We built a system from the ground up, which allows us to give devices to patients. Whether information is captured in a primary care office, whether we do an enrollment with our own operations staff, we put that into a database, we bring the data into the Partners system, into something we call a remote monitoring data repository. Then it's made available through other services to wherever else in the system it needs to go, whether it's a specific application. In one instance, we capture weight for patients for our weight center, our barometric surgery center, and that's a very specific application. In other cases it's more general, electronic medical records, they can call in if they want and begin to incorporate that data. That's our next hurdle right now.

Partners, I think is, in many ways we're lucky and in many ways we're not that we were very early adopters of technology; we've had an electronic medical record as long as anyone can remember, since Harvard and MIT first got together and invented the thing, which unfortunately means our electronic medical record is a huge legacy system. For the technically minded here that means it's probably a million lines of undocumented spaghetti logic. I don't want to disparage our informatics people, but it can be difficult. It's big and it's homegrown.

We've gotten much better at integrating that data, and we now have mechanisms to do it, but the question remains, what data does someone want to see? I can take 1,800 blood pressures for a person at home a year because they monitor themselves very diligently, and no one wants to see 1,800 readings when they open up a medical record. The question now revolves around not so much how do we do it, we can make the technologies work, but what do we do with this data? So today, for the most part, it sits. When data comes from that source, people know it's remote monitoring data, it was not clinically obtained inside the clinic, and it can be treated as such. It's flagged as such and it moves through the system as such. The question now remains how do we show it and who wants to see it, and in what ways?

Courtney Rees Lyles – Univ. of Washington – Group Health Research Institute
I would just like to echo that. We also created it. Ours are a little bit of a smaller scale ... pilot intervention for patients, so we also created our own systems. The remote monitoring data went into its own database online and then the patients could go on and access that through their electronic health record, as well as the provider involved in the trial. But it was uploaded and sat there and they received feedback on their phones and it was a static interface that was then fed into our electronic health record.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Do you have anything to add?

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
Well, it's a little bit different because we're not coming from the institution. We do have several institutions that are part of our membership, but the question really being on the aspect of where this data goes. There's a number of our members who take that data, they have actual medical devices which are

approved by the FDA, which then can translate that data into meaningful information for providers to really be able to analyze that and then target appropriate care for the individuals. But I'm answering from a very different perspective than the one that you were asking. I just want to bring up the perspective of our systems, there are services, back end services, back end solutions which do a number of functions but they're part of the general care. It's complicated because it's not like the data just goes and get funneled to someone that gets to read it and trends it according to whatever, these are actual medical devices that are FDA cleared to do a certain thing and a certain function that then get used by doctors. So that's yet another aspect of what you're asking. I just want to make sure that you also have that perspective.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. I wanted to actually just turn to the phone for a minute. We have some members on the phone, Joyce, Don, and Dixie, I'm not sure if anyone else has joined on the phone, but I wanted to ask if you all have any questions for this panel?

Joyce Sensmeier – HIMSS – VP of Informatics
Nothing here, Jamie. I'm good.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I have a question, Jamie. I found it interesting, though not really surprising, that the patients never mentioned privacy or security concerns. But my question is, have privacy and security regulations and requirements, have they ever been a barrier to what you're attempting to do? Especially those of you who are working from within the regulated health systems, I'd be interested in hearing what you have to say about that.

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
They've never been a barrier. I don't think they've ever prevented us from doing something. They have made us do it thoughtfully and slowly, which is exactly the point of why those regulations exist. I'll differentiate in my experience between the program world and the research world, so they've never been a barrier to research. In the consenting process for research, we can often call out if there's an issue, if we want to use a smartphone that may or may not meet some certain standard, we can call that out and patients can give their informed consent to be part of that research trial. In the program world, however, we must do things much more thoughtfully, so they have slowed us down. They're one of the reasons why maybe the most cutting edge technologies that are out there haven't immediately jumped into our systems. Building systems that can handle the kind of encryption, the kind of tracking of access, the logs of who does what and touches what data, takes some time.

That's one of the reasons why to run our programs we've had to build this proprietary system that knows who enrolls what patients when, who looks, where does the data go, when did it come in, where did it go out to, etc. So although it hasn't stopped us, I think it has slowed us down. I don't know that that's a bad thing, in many cases, because privacy is such an important issue. Whether patients ask about it or not it needs to be protected. I hope that helps.

Courtney Rees Lyles – Univ. of Washington – Group Health Research Institute
I agree. I think on every level it did slow down the development and implementation phases of our research, in the sense that, again, we're working within a system that had pretty sophisticated electronic health records. There were a lot of already built security and privacy standards in place that we obviously continued to uphold when we built any additional standalone systems to feed into that. Then through the human subject approval and those processes also obviously somewhat newer topics for them to consider and to think over and made our consent process a little bit longer but very informed, I would say, and spent a lot of time at the beginning of trials talking with patients about this. Perhaps then related to the end outcomes when we asked patients about their concerns about security, perhaps that was an influential determination that they did not have concerns because we spent a lot of time up front talking about what was going on with all of the information and devices that they would be using.

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs

With regards to the members that are involved in back end services, privacy and security issues are of paramount concern. I know of a number of member companies that have been interested in performing those types of services, which have shied away from doing so because there are really concerns about how the different relationships through HITECH have changed. They've strengthened up business associates to have some of the same treatment as covered entities, etc., so it really has been a concern for the industry and namely for those that are involved with handling patient data directly. Especially if they do fall under being a covered entity or a business associate, there's a little bit of a lack of clarity sometimes given the fact that there are so many cloud-based services in information systems as to where the handoff happens and who's actually transmitting and so forth. That is an area of vital importance to the industry.

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
If I can add one more quick comment to that. I think Robert's right, the barrier right now because of privacy and security is affecting the smaller companies with cutting edge technology that may be thinking about getting into this area. They'll come to us and say this would be cool if you would use it, and we ask yes, but, yes, but, yes, but. By the time we talk about business associate agreements and the things that are necessary, it scares many of the small cutting edge companies away, or at least makes them go back and re-think their business model. So that's where the barrier is.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Any other questions on the phone?

Joyce Sensmeier – HIMSS – VP of Informatics
Jamie, I did think of one other question. This would be for Rob and for Courtney. With Robert's testimony from the Continua experience and the number of implementations that they're seeing of standards based technologies for these home devices, I'm wondering if you had leveraged those standards or that type of technology before and maybe you just didn't describe it. Or if you hadn't what would be a way for you to become more aware and looking for the adoption of it, I guess would be my question.

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
Sure. I guess I'm going to ask a question back. I'm a little unclear as to what you mean by "leverage those standards."

Joyce Sensmeier – HIMSS – VP of Informatics
Sure. It sounds like there has been some success using the Continua standards that have been developed to getting those adopted at various places, we heard Cleveland Clinic, Providence Health were examples that were given. I think that is a good example for us to think about the fact that there are standards available for this but they're not necessarily being leveraged readily, or widespread, certainly. So my question to you is, first of all, were you aware of those, and are you using them and we just didn't talk about it? Or, if you're not, how could we remove the barrier for that type of use? Does that help?

Robert Havasy – Center for Connected Health – Technology Strategist and Operations Manager
There are two Robs on the panel. It makes it a little difficult. Absolutely. The Center for Connected Health is one of the founding members of Continua, so we're very well aware of the standards and the work that the group has done. Many of the devices that we use have in fact come from Continua Alliance members and have Continua's standards behind them. It is something we look for when we're looking for new technology, but it's not something we exclusively seek. So the beauty of the Continua standards and the way the alliance really works is that it's not quite like the UL symbol. We'd love to see it there, but many companies can begin to adopt these standards without going through the whole certification process. So the devices we have now usually have some Continua compliant components in them. A few of them have made it through the full certification process and are beginning to reach the market now, but yes, we've absolutely leveraged them and we do this every day.

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs

I would only add that the membership works towards identifying standards that really offer true interoperability in the sense that they know that they're going to work together. Because what happens is that once we develop guidelines then we have this entire test and certification program so that literally companies can come together for what we call Plug Fest three or four times a year, even more, to make sure that their devices do work together in the marketplace. That doesn't mean that these devices only work with Continua certified devices. They can work with any other device that has the common standard that they may be using. Again, I go back to the same three that I've mentioned, only because those are the ones that have been adopted by Continua. So USB, which is really a wired standard, just like your common USB that you use on a computer or a laptop, the wireless standard Bluetooth, and ZigBee, and we're constantly working and trying to identify others.

One that we're working on currently is for NFC (Near Field Communications), which may not be as prevalent in the United States, but is definitely something that's used around the world. In the future you're going to see more interfaces that will be coming out of Continua. It's just it takes a lot of time. Developing these things has taken, obviously we've been in existence for five years, and there's a question that I'm often asked, which I'll posit very openly, why aren't there more Continua certified products? Currently we have over 30. The reason being is that these take time. Once these devices go through what they go through internally, they still have to go and be developed by each company. Product life cycles take up to two years, sometimes even three years, and most of them are medical devices which need to have FDA classification, and that, in and of itself takes sometimes a lot of time.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Once a year I evaluate Continua for part of the Gartner ... cycle evaluation and just by coincidence, this is the month. I'd like to state some assumptions or some observations about it, and Robert, have you correct me if I'm wrong. You've emphasized the adaptation to the underlying transpoint technologies and lower layers. But my understanding is that Continua publishes specifications for a stack that includes how to format and handle clinical data, how to identify the patient and things like that. Is that correct?

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
That's correct.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I further understand that the complete stack in the form of a final specification was only available last summer. Is that right?

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
Yes, I believe so.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So in terms of this issue of how far along it is, we would not really be expecting that it has been widely rolled out, but we have to be very sensitive to the experience that we as consumers had with every standard interface we've ever dealt with, Bluetooth, USB, printer connections to Windows. Eventually, they get it right. But we're usually exposed to three or four generations of products before they get it right. It would be important for us then to understand that the patients, as Courtney and Robert have honestly described it, can't be the guinea pigs for those four rounds of trials. So that's why I was asking about the effect of these trials that you've had. We need to understand where we are on the evolution curve of standards like that.

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
If I may, you're absolutely correct, and I'm very glad that you brought that up because I didn't want to go into the nerd side of what I was going to talk about, which are the different versions of how we've gotten to where we are. But in version one, for example, we literally identified IEEE standards, which are the version one cases of USB and Bluetooth, I believe. Through that scope, that interoperability between

version one, that personal area network interface that went into an application hosting device, from there that spoke to yet a back end system, and that back end system dealt with exporting vitals and vital medical data. Some of the languages that were looked at then were HL-7, SNOMED CT, and SAML 2.0. Then from that point going back to the PAN we had to strengthen it a little bit, so version 2 dealt with a lower power going between V1 into the application-hosting device. There's also the Win interface, which at version 1.5 started dealing a little more thoroughly with focusing on sensor data uploads. So, yes, what you're saying is very important because there have been multiple versions of what Continua has worked on and they take time, they really do.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I appreciate the ability to get the propeller on my head spinning. I think the question we need to ask as a committee is, is there a small collection of devices now where the consumer experience lives up to the challenge that Robert and Courtney have set for me? If they are, then we would like to, and this is me speaking as a proposal to the workgroup, we would like to advocate getting more of those as quickly as possible. If in fact the evaluation of Continua shows that it's along the path but still has some of that evolutionary work to go, then we need to look at whether there's another option and so forth and look at it. But what can be done in the interim, would be a better way to say it, I guess. Thanks.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. We are at time for this panel, so I want to thank our panelists very much for excellent testimony and discussion. We just have a very short break while we're changing up the panel table. Thank you very much.

I want to welcome our Provider panel and get the discussion started here. We do have a couple of folks who stepped out for coffee, but I think we're going to go ahead and get started right away anyway. Thank you all for coming in today. I very much appreciate you being here and being willing to discuss the set of issues with us. We have Dr. Julian Goldman, Scott Evans, Dr. Hiatt, and Sara Toscano. I really appreciate you all being here. So without further ado we'll start with Julian and go through the panelist presentations.

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
Thank you very much for inviting me here today. I'm looking forward to sharing information and I think I'm especially eager to hear your questions. My name is Julian Goldman. I'm a practicing Anesthesiologist at Massachusetts General Hospital, Medical Director of Biomedical Engineering for Partners Healthcare System, and since 2004 I've been the Principal Investigator of a research program on medical device interoperability based at the Center for Integration of Medicine and Innovative Technology in Boston. Recently we were awarded an NIH grant that brought us into the SHARP family of grants, that would be relevant to our conversation today, I think.

Medical device interoperability is necessary to lay a foundation for the more comprehensive improvements in patient safety, quality and efficiency that can arise from point of care clinical systems integration, incorporating rich data from medical devices. While we have seen great strides in achieving medical device interoperability, there is much more to be done to improve the system wide effectiveness of interoperability. The absence of effective interoperability presents significant barriers to the achievement of a national vision of using EHRs to transform healthcare. Integration is the key, integration. Integration of data from medical devices in order to improve EHR data quality and add error resistance to clinical care I believe is the real goal.

We must understand that interoperability is a key ingredient of integration if we want effective, efficient and affordable integration. A typical HIT perspective on the scope of medical device interoperability for many practical reasons is the transfer of a subset of clinical data into the EHR. This subset usually includes ECG derived heart rate and episodic systolic and diastolic blood pressure measurements and it is typically that data which is available at the gateway node. That data subset, however, usually excludes things such as ECG and blood pressure waveforms, alarm status information and alarm limits, and medical device configuration and management information. Some of this data may be readily available at the device interface, but it is not necessarily transferred to the network beyond the gateway, thus

becoming unavailable for many applications. This has been very frustrating for us at Partners Healthcare, and has stood in the way of several quality improvement projects for a number of years. Here are three examples that might provide insight into the limitations imposed by our current standards and technologies.

Example one: Partners Healthcare has been implementing a system wide clinical documentation system, which was to include comprehensive medical device data acquisition. However, given the limitations of current medical device interfaces, we have had to markedly decrease the initial scope of data acquisition by reducing both the data types and by eliminating a number of widely used devices such as infusion pumps. Due to the non-standardized handling of patient ID to device binding, we had to discard most clinical data acquired during in-hospital patient transport.

Example two: Incorrect clock times. Computers obtain the correct time using a network time reference such as Network Time Protocol (NTP), but the clocks in most medical devices do not synchronize with the network. Consequently, as the medical-device clock drifts, clinical data is exported to the EHR with an erroneous time stamp. These time inconsistencies may confound the interpretation of clinical events, undermine the integrity of the EHR, and complicate the implementation of clinical decision support tools. Our research program is working on assessing the root cause of some of these problems and developing an industry workgroup.

Example three: Interface performance. Even when using manufacturer-provided electronic data interfaces, data acquisition may be neither simple nor benign. For example, recently in our research lab we discovered that an Intensive Care Unit ventilator shuts down and reboots, while actively ventilating, when prompted to communicate data to the EHR above a certain bandwidth limit.

What should be our goals? Many current medical device interoperability activities are based on a least common denominator approach of using current standards and current vendor capability to down-select clinical use cases that can be implemented with existing standards. This leaves important, clinically meaningful capabilities out of scope and allows little room for improvement or innovative use of the data. In view of the importance of effective medical device interoperability, we should instead be forward-looking by following the industry standard methodology of product development, in which one begins with clinical and functional requirements to ensure that the results that are developed are meaningful. These requirements should be used to perform a gap analysis of the capabilities of current standards to enable innovative healthcare solutions. The National Institute of Standards and Technology has been collaborating on a project to develop gap analysis methodology for medical device interoperability standards.

Finally, hospitals have had to become system integrators. Many hospitals lack resources and capabilities to perform this function competently now. This is further complicated because many vendors are reluctant to disclose complete device interface data. Furthermore, there is a national shortage of clinical engineers with appropriate training in medical device informatics and health IT system integration. The challenge and cost of system integration will continue to detract from the value of EMR implementation and the acquisition of meaningful and useful data from medical devices. Please see my written testimony for more detail on these and related topics. Of course, I welcome your questions. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Next, we'll turn to Scott Evans.

Scott Evans – Intermountain Healthcare – Senior Medical Informaticist
Good morning. Intermountain Healthcare has been actively collecting data from medical devices and putting that data in our EHR for over 23 years. Initially, we began with bedside monitors, ventilators, pumps, and we have a number of other devices. Currently, we're actively interfacing data to some CAT pumps, enteral feeding pumps, and portable monitors. We have also created numerous programs that allow clinicians to access that data, not only anywhere in the hospital, but also in their homes, in their offices, clinics, or InstaCares. We use the data from the medical devices in a number of clinical decision support programs. We also use the data to generate a number of alerts.

One of the main problems that we have is every time we interface to a device, not only the type of device but also the vendor. We have a lot of middleware that we have to develop. There's also a lot of communication back and forth with the vendors, how's the data laid out, and on and on. It would be very nice if we had standards for the output port types, data protocols, frequency and methods for acquiring the data. Also, there are no actual common languages that are being used. Some of the devices use textual data, some are coded data; some of the coded data may be in XML; some may not. Each of the vendors interpret that in their own proprietary way. So that's one of the main issues that we probably have that probably takes us longer than anything else.

Not only would it be nice to have a common data language or data dictionary, it would also be nice if we could map that data to, say, LOINC codes also. However, USB, Ethernet, the RS232 standards have been very helpful. These have greatly helped us get the data into the device where we can take that data, store the data, retrieve the data, and also analyze that data. In the last few years a lot of the manufacturers have actually taken their devices and they're collecting the data from the individual devices and placing them on gateways, so we only have to connect to the gateway. Another issue that we have is that a lot of these devices are not able to send us all of their data. They're only able to send part of their data. A lot of the older devices do not even have RS232 ports, thus, there's no way to get a hold of their actual data. For a number of years Intermountain Healthcare has only purchased devices that we can connect to.

One change that would make it more effective and widespread would be use of wireless, DL3 or DL4 technology that's out there. This would be a great way to not only get the data from the medical devices, but also send data to the devices, even from the patient homes. Getting the data is often the easiest part. Deciding where to put the data, how to put the data, how to store it, what form, and how much to store the data is always something that we have to determine for each individual device. We believe the data from any type of medical device should be placed in the EHR, implemented devices also. We want to know not only who the patient is, patient identification and also all the data coming from the medical device, we also need to know what the device is. Is it a ventilator? Is it a pump? We also want to know what the brand is, serial number or some type of a unique ID. It would also be nice if each device had a radar frequency ID. We want to know where that device is and where that device has actually been. We can take that data to go back and look at repair histories, recalls, where that device has previously been, we can track down infections there, billing data, and supply chain management.

There are a number of the meaningful use stage one objectives out there that medical device data will play a part. For example, you need to record the blood pressure in the EHR for more than 50% of your patients. The ability to exchange key clinical data will also contain data from medical devices. We believe that the automatic collection of that data into the EHR will be a key part there. Also, based on the FDA's new MDDS rule, Intermountain Healthcare is now a medical device developer, and we will need to comply with new regulations. We're going to have to determine all our programs ... or into an actual MDDS. We're going to have follow the FDA's QSR guidelines, and report anything of the errors that we find.

The big issue that we have right now is how much time and what the cost will be for Intermountain to go back and follow up on this. Intermountain's already created a team to go back to determine that, but also just trying to get a handle on all the different programs that we have out there that are going to fall or be classified as MDDS. A big issue that I have, and a lot of us have, is what is the time and effect going to be for us now to get these new programs in, and update programs in a timely manner. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Next we'll turn to Jo Carol Hiatt.

Jo Carol Hiatt – Kaiser Permanente – Chair, National Product Council
Thank you very much for the invitation to be here today. I'm Dr. Jo Carol Hiatt and I'm here today on behalf of the national Kaiser Permanente Medical Care Program. We're the nation's largest integrated healthcare delivery system, providing comprehensive healthcare services to more than 8.7 million

members in nine states and the District of Columbia. I serve as Chair of Kaiser Permanente's National Product Council, which oversees contracting for everything, equipment and supplies, other than pharmacy, that we use in the care of our patients. I also chair our Interregional New Technologies Committee.

As part of our commitment to the highest quality care, Kaiser Permanente has made a significant investment in a program-wide Electronic Health Record system, Kaiser Permanente HealthConnect. Kaiser Permanente strongly supports the adoption of health information technology through provider incentives for meaningful use and are currently working toward meeting meaningful use objectives in the first year of stage one. Excluding medical imaging, approximately 250,000 biomedical devices are in use in across Kaiser Permanente today. Currently 85% of these devices are not attached to our enterprise network; however, we expect an additional 30,000 devices to be integrated over the next few years, nearly all from anesthesia, laboratory and patient monitoring. We've undertaken a concerted effort to reduce variation in biomedical device use and management across the regions, and a critical element of the initiative encourages common standards across vendors through our procurement process.

We've partnered with Dr. Goldman and others in MD FIRE, and other tools, however, suppliers invoke absence of standards and declare they cannot commit due to uncertainty of the requirements. Adoption of standards compliant interoperable devices in systems will enable the development of innovative approaches to improve patient safety, healthcare quality, and provider efficiency. For example, the ability to synchronize taking an x-ray with a ventilated patient's breathing cycle clearly improves image quality. Unfortunately, the ability to interconnect and synchronize these devices is not available today. There are many other examples where interoperability would improve patient safety and result in better outcomes.

Kaiser Permanente has developed multiple orthopedic, cardiology, and cardiothoracic registries and is currently expanding to other specialties. The Total Joint Replacement Registry is KP's first and largest interregional registry and is now the third largest joint replacement registry in the world. The benefits of standardizing unique device identification will reduce medical errors and facilitate recalls of implanted and other devices. More generally, device identification will improve supply chain management, inventory control, impede product counterfeiting, and aid in disaster recovery. The unique device identification system would provide uniform labeling and consistent data across Kaiser Permanente's interregional registry efforts, enabling comparative effectiveness research among KP's research collaborators and with other countries, including Sweden, Finland, Norway, Australia, and Denmark, with similar registries.

Kaiser Permanente supports the continuous improvement of healthcare quality and patient safety promoted through meaningful use and through healthcare reform. We have already invested in technology and taken steps to integrate medical devices in our systems. However, we believe that our own efforts to integrate devices, as well as the efforts of those across the industry to design, develop and implement such interoperable devices, will be enhanced by the adoption of standards. We have not been as successful as we would have hoped in encouraging our supplier partners to develop integration with our EHRs as we have been with image storage and PACS. Driving toward consistent and interoperable standards for devices will encourage innovation that focuses on improving clinical outcomes and patient safety through accurate data available to providers and patients and EHRs.

Thank you to the committee for the opportunity to provide this testimony. I'd be happy to answer any questions.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Next, we'll turn to Sara Toscano.

Sara Toscano – VAMHCS – Coordinator, Clinical Information System
Hello, my name is Sara Toscano. I am a Coordinator of a Clinical Information System at the VAMHCS, which is the VA Maryland Health Care System in Baltimore. What we have experienced as far as healthcare devices and our barriers as far as device interoperability is that some devices overcome interoperability issues easily. The cardiac monitors that we use output data easily in any electronic health record with relative ease. What we have found is we want to interface things such as balloon pumps or

IV pumps, that we would have to contact a vendor, who would then have to develop a custom solution, which could be costly and time consuming. Many of the interoperability issues that we've experienced within VA in the implementation of our electronic health record had actually been resolved through close collaboration between the vendor and the VA's commitment to finding a solution.

The limiting factor is the level of standard adoption and maturity of some devices. Standards enable interoperability, which in turn enables automation and improves efficiency and quality, because it eliminates relative or error prone activities such as manual entry. If a clinician wants to enter device results manually into a flow sheet, they could benefit from standards ... and interoperability. Standards ensure that the medical device's report results automatically into an electronic health record or a nursing flow sheet. Standards may also help manage personalized device configuration. If a person's on one ventilator and we change him over to another ventilator, that information automatically is downloaded from the previous device to follow into that patient's record. Ensuring that medical devices are associated with the correct patient record allows us to provide safe care.

In the current marketplace vendors have no incentive to make their information systems interoperable with other systems. There's actually a disincentive to do so because non-interoperable systems force an enterprise to continue to expand with one vendor, versus being able to seriously consider solutions with other vendors. This has been an ongoing problem for many years in the private sector, and is now a challenge for the VA that we need to address as we are in the process of implementing multiple clinical information systems into our ICUs and ORs.

We've experienced several problems that could have been prevented if there were some standards. The best example I can give is the GI scope software that many of our VAs use does not interface with our computerized medical records system, and as a result providers were instructed to cut and paste reports into the CPRS note. Occasionally, reports were pasted into the wrong chart. If there was technology to move these straight into the electronic record we would not have had those errors. The site that had this one situation, investigated and found an error rate of 2% of copying and pasting. The site reviewed its process and decreased the lag time between the scope report generation, and the availability in our VISTA imaging for review.

It is important to note that VHA regularly issues patient safety alerts, which describe safety risks and how to correct them. They are posted on our Internet and our Intranet and we encourage health systems to use VHA funding to expand knowledge of sharing help to improve the way care is delivered. Some examples of VHA patient safety alerts include CPRS, Changing Medication Schedules May Leave Incorrect Medication Administration Times, possible blood contamination through hemodialysis machines, and misidentification of patients resulting in delay of surgery. Physiological monitoring of critical care areas is considered highly standardized and there's little debate on how to measure a heart rate, a blood pressure, or central venous pressure. Standards in the ICU are ever changing and I would consider these very mature, evidence-based practices that dictate the change in processes in order to provide exceptional care to our veterans.

Standards dealing with integrating medical devices with nursing applications are also mature, but these standards enable documentation of processes and procedures with real time standards, and once in place they enable a single vendor integrated solution. We need to distinguish, however, between the state of standards and the state of standard application. Application of standards, especially standards based nomenclature and technology is still limited across the industry as a whole, so industry leaders are making progress in this area. I can speak specifically to VA. As we are putting into place our new information systems into the ICU we have come together to create a standard terminology in order to make the multiple systems actually relate and speak with each other so we're all using the same word, lung sounds are the same, a blood pressure means a blood pressure.

The less mature standards are related to devices, and these have to do with technologic interfaces. A real problem occurs when you try to maneuver multiple administrative layers to determine if interfaces are impossible. If a new device is possible, the site wishing to use the device must first contact the vendor, the vendor must collaborate with the developer of the device, and the developer of the device must

determine if they're interested in allowing interface to their product. An opportunity for improvement would be to establish standards requiring companies that contract with government agencies and who would like to remain in good standing to agree to work with others. The standards dealing with ventilator modes of terminology and nomenclature are still in the early stages of development and also are less mature.

Clinical standards are by far the most important area where standardization is most relevant to EHR technology, where ... end users must be understood and well documented before an EHR or medical device can be interfaced. We all need to understand how healthcare technicians are doing their work in order to understand how interfaces will affect workflow and how our ability to retrieve data for import will function. Most VHA performance measures are dependent upon reliable data. We get this when we have a seamless mechanism. Data monitoring extracted from critical care monitors or system devices such as ventilators, balloon pumps, enhanced cardiac output monitors, and all the interventions of the nursing staff populate into a computer system, which validates our compliance with the clinical practice standards.

The meaningful emphasis in the adoption of the electronic health record is any work intended to improve usefulness will overall improve the adoption of the EHR in the United States. Consistent adoption of standards and ... technology would remove some of our barriers. Unlike information systems, medical devices often undergo long product life cycles, which take much longer to upgrade and modify, not only if they are registered products, but because they consist of both hardware and software, therefore, designing and developing and testing new or revised medical devices requires more time. VA medical centers are currently in the process of installing multiple off-the-shelf clinical information systems from multiple different vendors. For certain telemedicine applications this has raised rather complex and potentially costly issues for the VA centers, as they are now less able to share information and share resources between the VISNs. In the current marketplace, again, the vendors have no incentive to make information systems interoperable with other systems.

If I could wave a magic wand, I would have all devices use the same standards for outputting data so that the interface in the EHR would be no more difficult than consumer product synchronization is today. For example, if I were to go buy a new Bluetooth wireless keyboard for my laptop it would take just a matter of minutes to get it synced. A contract did not have to be negotiated with the vendor of the device to have a code written. It was quick, intuitive and accurate. It would be easiest for a nurse to have some sort of barcode scanner or some sort of identifier that could sync in the patient record to the EHR. Ideally, it would be a device and vendor certification requirement so that the medical consumer would be assured that any device being marketed would pass interoperability standards. Another thing we'd like to see if we had a magic wand was to upgrade all old standalone devices to become networked, to be able to communicate information in the enterprise using standard technology protocols.

We would love to have a sandbox to implement a test environment, separate from healthcare settings that would be controlled by the VA, to ensure that systems could work interoperatively within the VA healthcare setting. This environment would allow authentication and verification that these systems actually have the ability to communicate with other systems. Manufacturers should include standards-based real time location system technology internal to their devices so the users would not be able to apply external tags and deal with operational problems and costs associated with regular battery replacements or tag replacements.

What we like to see in our electronic health records is what I think we already do within our CPRS. We put in a warning that actually has the name of the device that's implanted or the type of procedure that may have an identifier to it being in a manufacturer or some sort of special transmission stamp, we put that within our records. Medical device data is not explicitly referenced in the stage one measures. The National Institute for Standards and Technology approved ... methods for stage one, but do not require medical device data to export or input the same way it requires laboratory results or ePrescriptions. The medical devices will contribute to the discharge summary's clinical decision support, such as for ventilator acquired pneumonia, bloodstream infections, rapid response advisories or predictive trends, and patient summaries, which is another requirement explicit to stage one.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. I appreciate—

Sara Toscano – VAMHCS – Coordinator, Clinical Information System
Thank you. I apologize for going over.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No, that's okay. I appreciate it very much. We do have your written testimony and I think we'd like to open it up at this point for some questions from the committee. Before I go to questions from the phone, I know that Chris Chute has to leave us shortly, and so I wanted to enable him to go first in the queue here.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I'll be back. Three comments: One, Julian, I want to welcome you into the SHARP community and I'm actually delighted that the device issues and related technologies that you're exploring will be part of that exploratory activity. But I do have a question for the panel, and Scott, let me focus it on you, but Sara, you've touched upon this to some extent.

I've been hearing this morning two modalities of device standards, if you want to think of them that way—and I've debated this with Todd Cooper for the past ten years or so. Although he's not paying attention, and specifically there are, if you will, communication standards, which I submit would include things like Bluetooth, RS232, wherever you want to be along that spectrum. I would distinguish that from what I would characterize as content standards and vocabularies, value sets, that sort of thing. Y were very explicit, Scott about articulating them as distinguished, and Sara, you had mentioned correctly that the VA has been quite proactive in trying to have common and consistent vocabulary standards across it. I understand Kaiser is too, everybody is. But here's the question, to what extent do you feel that content standard specification exists at a device level or should the fact that they are applied to devices be transparent or invisible to the user? That is to say that the device community would adopt the interoperability standards and content standards, by interoperability I'm referring now to content standards, of the larger clinical community independent of there being applied in a device.

Scott Evans – Intermountain Healthcare – Senior Medical Informaticist
That's a hard question to answer. Quite often we get very good help from the vendors, but there's a lot of going back and forth. Some of them connected their devices to EHRs previously and some of them had not. Quite often when they give us the data the first time it doesn't work. They have left this out or left that out. The content would be very nice if we explicitly knew what all the actual data elements were.

I'm not sure if I'm following your question. We can then do the mapping to LOINC, SNOMED, whatever, but it would be nice if they had already done that on their end also. Now, whether we can get them to do that, that to me would be more of a phase two or a phase three. Let's get the network device part, message layer and the content. We need to at least get the data elements. So when you have a pump you know what the data elements are, so the pump vendor here, the pump vendor there, we get all the data elements. Some of them can give us part of the data elements. We've had to have them go back numerous times, develop programs on their end just to get the data that we actually want over. We tell them what data elements we want to have and they always come back to say, okay, here are the data elements. I want you to know we want all the data elements. We want everything. We'll take care of this on our other end. But we have to do that for not only every device but every vendor also.

Sara Toscano – VAMHCS – Coordinator, Clinical Information System
We're currently working on the electronic records that we're utilizing ... right now. There are actually three vendors that we can utilize right now. What we have done is put together workgroups where we challenge every vendor to give us exactly the same thing so that across the board they can speak through analytics or whatever we choose to use. We have expectations that we want every piece of data that we can possibly have. If we have a device that puts out that data that we have and an intervention for or a space for we want that data, so when we get in these workgroups we talk about every possible piece of data we can get from a device. So that if it's available for us to map to that cell, if it's not there

we've got it for the future, we're trying to think very forward thinking. By us doing this now, it's going to affect anybody else that purchases these devices in the future because they're going to set up a new code that's going to allow everybody else to be impacted by the detail that we're looking for.

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
May I add something? Under our medical device SHARP grant, several months ago, we started a project in collaboration with Kaiser Permanente and the VA and several other hospitals to start to generate what we're calling a medical device interface data sheet. A list of all the things that we need, all the data elements that we need from medical devices and that we wish medical devices would use, could consume. So it's essentially a wish list that will then be staged into implementation stages. After we propagate the lists for top devices, we have about 25 devices selected, once we reach the point where we have that information from the hospitals that are involved we already have plans, and have had the meetings to roll that out to medical device manufacturers so that they can tell us what they think we're missing, for example. Then provide that as a common compendium to anyone who needs it for standards development and so forth.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Can I follow on? That's very intriguing, Julian, and I think that's a positive step forward. However, I've observed the world as, if you will, those who are thinking about this from a device centric point of view and those who are thinking about this from an enterprise or a patient-centric or whatever alternative universe you want to think about. That is to say, these ... that you are collecting, to what extent are they harmonized up front with the larger enterprise data representation space?

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
They are a device centric perspective, that is, being harmonized from the very beginning with input from a very broad perspective. So that, for example, one of the EMR vendors that we met with at HIMSS around this project, after they finished jumping up and down excitedly that we're moving this forward, told us that they could tell us things that we might be missing about what they need in the EMR to do a better job with the data. That's perfect. Then the medical device manufacturers that we spoke with said, well, make sure you include these capabilities of our specific devices, because we have some unique attributes that we want represented, at least in a common compendium.

We're not deciding or advising what should happen with that information, we think that forming that compendium will be of value because it could be used by everyone in the community regardless of what they do. There are other lists and other standards that include this information, so of course a subsequent step is to map these things to any existing standards that already represent the data. Our goal is to start collecting the information and the frustrations of people who are trying to perform integration or advanced applications and are confused as to why they can't get the data that we need, and we just heard that from the other panelists.

Jo Carol Hiatt – Kaiser Permanente – Chair, National Product Council
If I could just make a quick comment regarding some of these unique special capabilities from a given supplier. I would caution the group to think carefully about this because many of these may not really be useful data elements in terms of truly improving the outcomes and simply add barriers to entry to competition and create some interesting challenges. Not all data is true information.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Before we turn to questions from the workgroup here in the room, I wanted to first turn to the phone, because we do have some members out there on the phone. Joyce, Don, and Dixie, I wanted to see if you had your cards up for this panel first.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I don't have my card up right now.

Don Bechtel – Siemens Medical – IT Architect, Standards & Regulatory Mgr.
... right now.

Joyce Sensmeier – HIMSS – VP of Informatics
Nothing from Joyce. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Then we'll go to Wes and then Stan.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Just a quick question. Under what circumstances do you import data into the electronic health record without prior review by a licensed clinician, anybody?

Scott Evans – Intermountain Healthcare – Senior Medical Informaticist
I would say what we do, especially the logic, all our clinical physicians port logic. There is a clinician champion behind all that, whether it's a pharmacist, a respiratory therapist, MD, they're the ones that basically direct all the data that we actually want. As we pointed out, we do want all of the actual data. Oftentimes we have got a part of the data and then as we get into maybe doing some clinical decision support programs we find that we want some other data elements. To get the vendor to then go back and access that data, that's a whole other six month, one year process. But we—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm sorry. I wasn't talking about the development time. I was talking about in operation, is it always the case that a nurse or someone else looks at the data and says it's artifact free, signs it, and then it goes into the electronic health record? Or, are there cases where data from the instrument goes directly into electronic health record and is available for decision making for rapid response, or something like that, before it's been reviewed by a clinician?

Scott Evans – Intermountain Healthcare – Senior Medical Informaticist
So you're saying each one of the data elements, now, before we go live that goes through months and months of—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
No, I'm talking about you've been—

Scott Evans – Intermountain Healthcare – Senior Medical Informaticist
... goes right into the—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
It goes right into the electronic health record with no review by a clinician.

Scott Evans – Intermountain Healthcare – Senior Medical Informaticist
Right.

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
I would say there are different cases, not only within Partners but in general. I'll be specific to recent examples within Partners, for documentation going into the anesthesia electronic medical record, that data does not require review if the default mode is that the data is acceptable. Since there is a clinician always present one-on-one, we flag data that might be …, so we handle that as the exception. For other environments, we use the other approach, one that's very common, which will require a clinical validation or some clinical acceptance to use the data, and some systems don't allow data that's too old to be accepted anyway. That's the other case.

The third case is a research initiative that has been funded over the last few years by the DoD through TATRC to look at data and to help to automatically assess data quality through a number of means. One of the points that I made earlier that we don't have access to detail device information such as signal quality or wave form data makes it much more difficult for us to assess data quality. There are many

examples in which we look at data in the EMR and we don't know whether that was real or …, because we don't have enough related data to make that determination.

Sara Toscano – VAMHCS – Coordinator, Clinical Information System
Within the systems that are used in the ICU, that data is always validated by an RN, except for the lab data, which comes straight from a laboratory connection through HL-7, and that's validated through them. But it is those things that we validate that actually push out our clinical decision tools and our advisories for our rapid response pieces. So we are dependent upon the nurses still validating, because the computer puts in whatever amount it tells her to put in, but it could be the patient's moving around and you've got a heart rate of 185 when they're sitting there at a nice 60 in its artifact. So we have to count on human factors still.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Sure.

Jo Carol Hiatt – Kaiser Permanente – Chair, National Product Council
I'd just like to comment from the perspective of some of the earlier panel remarks around the consumer or patient acquisition of information and what do we do with that. At Kaiser Permanente, our members do have access through KP.org and secure messaging to send information to their clinicians. And we do retain that as part of the medical record, but it is not entered in the same category. So, for example, someone measuring their blood pressure at home, that would appear in that portion of the record but it would not impact the actual record in the electronic medical record itself of blood pressure recordings it segregated.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
How about a patient's in a telemetry bed that's having various data collected, does that get reviewed by a nurse before it goes into the electronic health record?

Jo Carol Hiatt – Kaiser Permanente – Chair, National Product Council
To my knowledge it's all reviewed by a nurse before it's in.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
There are a couple of products out there that are being used now to adapt devices, particularly in the inpatient setting, to EHRs. Do any of you have any experience with using those and have they been … in their other selves, or helpful?

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
Can you clarify? Are you talking about middleware products?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I don't want to get into naming specific products here, but some examples are Sensitron and Capsule Technologies products.

Jo Carol Hiatt – Kaiser Permanente – Chair, National Product Council
Yes, Kaiser Permanente is using Capsule. It's being piloted at one of our large medical centers currently and will be deployed more broadly soon.

Scott Evans – Intermountain Healthcare – Senior Medical Informaticist
We have looked at those but we continue to develop our own. Also, I didn't understand the initial question. Some of the data that we do put in the EHR does get put in and basically it's verified by a physical therapist. But your data from the bedside monitors, that's going in directly. But we take the 50 minute median on that. We do keep the rest of the data back there, but what gets provided out there is the actual median.

Sara Toscano – VAMHCS – Coordinator, Clinical Information System

One of the vendors that I've worked closely with truly are discussing with us about using the Capsule Technologies. That's their big focus right now as they change over some of the less reliable interfaces that we've had out there allowing us to pull in the appropriate data that does—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So from the point of view of this, which is not to review specific vendors, we need to assess the ability of an agent between individual instruments and the EHR that as an opportunity to perhaps make progress in the interim, is that—

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
When we look at the products that are available today they're essentially a best effort to perform integration working within a space that has the problems that we have all enumerated. So what happens is in a sense one looks at a system put together with some of the middleware products and it has a veneer of interoperability and a veneer of functionality. There is value to using those products. But for example those products will pass data from a medical device and if the clock time on the medical device is wrong, that incorrect clock time is passed seamlessly through the middleware solution into the EMR.

Similarly, as those vendors will certainly agree, their hands are tied by the limitations of the medical device interfaces and so they themselves have to be very cautious not to do some of the things that I mentioned, such as shutting down a ventilator if one has the wrong command or excessive bandwidth request. They're aware of this and so they've had to build this intelligence into their system to overcome limitations. Essentially, there's value to those solutions, it's all we have today in many cases, but they are a veneer and we're skating on thin ice with some of the way we're approaching them.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
That's a very good point, Dr. Goldman. Could we just take a minute and define today in terms of all we have today. What I heard from you is a SHARP grant that's going on that can lead to a set of requirements that could be responded to by industry in terms of what's feasible that could then lead to the development of standards. Am I misinterpreting?

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
That was just a tiny sub-project in a much larger scope of a five year plan of work that I mentioned because it was applicable to that discussion. Would you like more detail on the scope of work?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I would like to know the path between the main line of your work and Standards and Instruments. What are the steps that would have to happen?

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
Certainly. We have been aggregating clinical scenarios or use cases from a number of different sources, identifying those that have a strong likelihood of improving patient safety and improving workflow in a number of different clinical domains. We're using those to derive clinical requirements and engineering requirements and quality and safety requirements because medical device vendors in order to deliver effective interoperability solutions must, in most cases, go through a regulatory pathway that involves the FDA. So that has to be considered from the beginning.

We're looking at available standards today, analyzing those, this work has already started, to see whether the standards can support the requirements and also simultaneously evaluating potential architectures. Looking at standards capabilities without looking at the architecture ultimately of the system or possible architectures, leads us to problems in the end. For one of those proposed architectures, the high level architecture that's been published in ASTM standard F2761 on the integrated clinical environment, so we're using that as a high level framework, not exclusively, but using that as a high level framework, looking at the requirements. We haven't gone very far down the path where we have a standards gap analysis, but we are moving in that direction. The work just started this year. Then what we will do is share back to the SDOs and frankly to the world, so the medical device manufacturers, what some of those gaps are and how those gaps might be closed. It will then be up to the SDOs and others to close

those gaps with our support, with information, and certainly with encouragement. That's a short version of a pretty complicated—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So add to that the time that the gentleman from Continua spoke about the development cycles for instrument manufacturers. The fact that a hospital typically has an inventory of instruments that were bought over at least five and perhaps ten years, I would come to the conclusion. I wonder if you would agree, that it's extremely important for the work that you're undertaking to go on, but at the same time we do need to keep in mind interim solutions as well.

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
I think what you said is absolutely true. I think what's most important is that the interim solutions and the forward looking solutions are performed in concert and collaboration so that we ensure that there's a pathway for legacy device connectivity and to transform those interim solutions into long term solutions. I think for the most part the middleware vendors that we've worked with and talked to feel the same way and they're willing to do that. So I believe that most people are at the table with that approach. Of course, there are challenges in terms of the revenue model for transitioning from some of these business approaches, but I believe most people are on board.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think, Dr. Hiatt, you wanted to comment on this question.

Jo Carol Hiatt – Kaiser Permanente – Chair, National Product Council
Yes, a brief comment about the middleware, this is Jo Carol Hiatt, is that it's really an additional cost that's been required and Kaiser Permanente has chosen to outsource this particular cost, whereas, Intermountain has done it themselves for a variety of reasons. But it's because of the absence of standards and lack of interoperability we are unable to, within Kaiser Permanente, build interfaces and constantly maintain and update them as the manufacturers continue to change their end of the product. So we've chosen to make that an additional investment, but it is a substantial cost that really theoretically is not necessary at all.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think Stan is next and then Liz.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I'd be interested in your perspective. Some of you mentioned that the vendor doesn't have motivation in many cases to produce interoperable solutions. A fair amount of this conversation actually seems sort of déjà vu to me because I know, and Scott you've been involved and others of you may, I'd invite everybody to comment, this isn't the first time we've talked about device standards. In fact, we created device standards and I'd be interested in your perspective on why the standards that were previously created haven't led to a solution in the marketplace.

Scott Evans – Intermountain Healthcare – Senior Medical Informaticist
Intermountain Healthcare, we were very active in pushing IEEE 73 protocol standard through. That's been 23 years ago, or 20 years ago. I know it was passed by a number of groups in 1992, 1995, and I think the ... Group passed it then. I think 1998 the European group even passed it. Basically what we heard back from there, the vendor said if we take this on this will add at least $1,000, and this is back in the dollars back in 1990, this will add at least $1,000 per device. They didn't want to be the first ones into it because then that would put the price of their device higher than the other competitors and on and on and on. So nobody was the first one in. That's basically what happened then. It was market to demand.

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
I think in a sense seeing what is working can be compared with what hasn't worked and also understanding that we are in a different era where technology was like voodoo. Now we have consumers that can interconnect to almost anything through standards-based approaches in consumer electronics from our SD cards that if you can buy a USB memory device in the aisle at Target, you know you've

arrived in terms of interoperability. So we have a different expectation now on the part of patients and clinicians. It just demonstrates, first of all, it takes more than standards. Standards are only one ingredient to achieve interoperability. That's very important.

The other is that they have to be the right kind of standards that are being considered and developed within a framework to achieve certain end results. The Continua approach I think has been relatively effective because, Continua really is two things that are happening at the same time. Number one, the companies and other organizations, Partners Healthcare and Kaiser Permanente have been founding members of Continua, got together and formed an alliance that allowed for information to be shared and use cases to be identified and then that group resourced the standards development process in IEEE. Those went along in parallel, well, not in parallel, they went along synergistically because what Continua Alliance was able to do was resource the development of test and validation and certification technologies in order to ensure that the standards that are being developed actually work.

As we know, just because a standard is developed doesn't mean it works. It has to be profiled and it has to be certified. So it appears externally a bit complicated but it really is very simple. There has been money put in together by a group of over 200 organizations now to resource something. That fit in real time into standards development so that the committee kept making modifications so that what looked like a good idea on paper actually resulted in something that was effective. The world was ready for that, and the businesses were ready to proceed because of home and telehealth being a Greenfield unlike in hospital care where we have a different business case. I think we can compare that and learn a lot about it.

The other thing is, I believe there are some examples in the early days of Medical Information Bus implementation efforts where companies tried to essentially put a tollgate on connectivity and have proprietary steps in the system. That obviously isn't going to work today. I think it isn't happening today as we revisit these things. I think to continue our approach as a general model has been generally effective. It was used because it was copied from other areas, such as the Wi-Fi Alliance, Bluetooth Alliance, and so forth. It's a very standard industry approach. I think there are lessons that can be learned from that.

Scott Evans – Intermountain Healthcare – Senior Medical Informaticist
... we've built our own RS232 to USB converters. I think it goes back to the vendors wanting to give up a little bit of the proprietary edge on what they see.

Sara Toscano – VAMHCS – Coordinator, Clinical Information System
That's what I was going to mention. I've been working with just the change in technology within how we're interfacing over the last five years, and what I discovered is early on when you would talk with one vendor they would talk to you to a certain point and then they would get tight-lipped. They didn't want to tell you anything because they would be afraid that you'd talk to another vendor. I'm finding that now they're actually talking to one another because they're stumbling into the same barriers and I'm actually starting to see these vendors speaking with one another in order to keep their contracts with the VA, but also in order to provide a better, safer product for our patients. So I think that there is a move. It's less proprietary.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Liz? Are you done, Stan? I'm sorry.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
One more, if that's okay, if we've got time. I don't want to monopolize. I am interested in, it's sort of a follow on to Wes and also in a sense to Chris Chute. If we look at this as the fundamental connectivity but then also as one aspect, that's RS232 Ethernet, Wi-Fi, that sort of stuff. Then the content, in the things that you're considering, especially Julian or others that are participating in standards activities are aware of, are you talking about the issues also of some of the things that came up, that there would be an exchange so that you could uniformly get an RFID from a device or an identity from a device, or standard ways for identifying the patient? Which I see as separate and very operationally important things,

separate from what's the code that you send for blood pressure or the code you send for heart rate, those other issues. Are those all finding their way into the requirements related to these devices? How is that going?

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
Easy question. I would say that as a community those ideas are finding a way into where they need to be. But item by item and standard by standard and requirement by requirement it's pretty tough going. I think one way to look at this is, again, to say that what we need is to take a step back and look at the broad requirements, look at what our expectations are for capabilities, functionality, and an architecture. Because I think the problem is not that the numerous standards committees are not extremely dedicated and willing and eager to create part of a solution. I think that we don't have an adequately clear framework so that everyone knows what they need to provide so that in the end we have something that is incredibly functional and can transform healthcare.

That's the role that I think we need to see especially facilitated by the federal government, and it has to be driven by clinical requirements and clinical use cases that become a common shared repository. Then folks in different organizations, be they in IEEE or HL-7 or ASTM or ISO/TC 215 or ISO/TC, you know the whole alphabet soup, at least would have a common vision and a common set of requirements. I think that has been one of the root causes of the fact that we have a bit of a mess and such a hard time coordinating.

Scott Evans – Intermountain Healthcare – Senior Medical Informaticist
Every time we deal with one of these vendors, for example, we're working with a vendor right now, ..., and they said they have the data and they can send it to us in XML. Well, it's been months now and we're asking for them to get a copy of the XML so we can at least go through, look at the tags, and see what the data elements are. But now we're waiting month after month after month. So they told us they have this, but it's always a waiting period before we can get it. I don't know whether it's for them to get legal permission to give us the data or they don't have the data. Oftentimes they say they have the data but it isn't ready yet.

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
Wouldn't it be nice if that was a requirement, that the FDA required that all the interface data was disclosed when a medical device was cleared through the regulatory process or another federal requirement out of ONC that that had to be disclosed and provided? It's really unfathomable as to why that isn't an absolute requirement as part of selling a medical device.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Now, I'm done.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Liz and then Wes.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Thank you for your input. Yes, it is unfathomable, but we are where we are. I noticed that each of you talked a great deal about what was in your four walls, which may be many, many more walls than four, but inside of your provider environment— I know that you had spoken briefly to who you're telemedicining with or remote monitoring. Are there any unique challenges to getting that data into your systems that are different from any of the things you've spoken about within your four walls? Anything unique that you need from us?

Jo Carol Hiatt – Kaiser Permanente – Chair, National Product Council
I think for Kaiser Permanente, the first concern that we have is the accuracy of the data source and being absolutely certain that that member is who that member says he or she is. It might be their neighbor, Sally, came over for coffee and said, oh, what's my blood pressure today or whatever, and being able to really validate the information. We're very careful, it's part of the reason many of our imaging devices are still not networked, many of our ultrasound devices in our OB clinics and other sites we don't have

verifiable patient verification, so we do not upload those into our archive, we're very concerned about making sure that there's data integrity in our data systems.

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
I would concur that data provenance is a huge potential problem and one that we haven't addressed. Related to that would be devices, exactly which device was used by someone. If we start to see values drift, we need a way to track that. The UDI as proposed will probably help, but it won't be sufficient if it doesn't include the device level identification. Knowing that the blood pressure was obtained with a blood pressure device could help if it tells us that there's a brand difference or some other difference like that, but we really need to know exactly which device that was, and that should be a network readable device ID.

Scott Evans – Intermountain Healthcare – Senior Medical Informaticist
So monitors, a lot of the bedside monitors we're pulling that data. We've been doing that for 20+ years. When that patient goes, say, for example, to the OR, or they go down to radiology, that then is unplugged and pushed down. We're currently working now with a portable monitor, so that way we would have the data down the hallway and everywhere. What we're struggling with right now, we're not really struggling with but we're dealing with right now is a way to uniquely identify that patient to that monitor, because we know monitor X is in room Y and we know the patient is in that room. But now we're dealing with how do we know that that is patient X all the time? Then when that monitor now gets passed down to the other room, how do we then take care of that issue? That is going to be something we're going to have to deal with.

Sara Toscano – VAMHCS – Coordinator, Clinical Information System
That same issue is also true with some of these IV pumps, because I know that there is the ability to wirelessly interface some of these IV pumps to a patient. The problem is that if you were to do that that device would have to follow the patient. Right now, the technology does not allow for it to flow from one area to the next, and it's something that we need to improve over time by just developing a standard set of how we're going to systematically pull data, that's just my opinion from my experience. What I'm hearing my colleagues say, that's a big issue for us, especially in intensive care areas in the ORs if we start somebody on a vasoactive drip in the OR. We'd like that pump to follow them because by taking something off a pump and putting it on the next pump you lose some of the value of the medication you're giving or of the monitoring that you're doing.

Julian Goldman – Partners Healthcare – Medical Director, Biomedical Engineering
It also gets to the point about, that Wes brought up, about the role of middleware and implied is it sufficiently effective. What medical devices should do is they should find a way to read or consume patient ID and then include that in the data stream. Some devices do that. Most of them don't. The middleware, one of the major functions of today's best middleware is to address that gap and to tie in the patient ID into the data stream or to provide that association and binding. It's a very difficult problem that's made much more difficult, as alluded to by the other panelists, with wireless devices, and that's obvious. I don't need to go into that. However, it's, again, one of those things that needs to be addressed at the device level. Trying to fix it elsewhere in the system is a recipe ultimately for error and lack of success.

Scott Evans – Intermountain Healthcare – Senior Medical Informaticist
We've been using wireless pumps now for a year and a half, so we had to develop a program on EHR where the nurse will actually go in. There's a device number on the pump and it will say device number X is on that pump, a similar thing that we may have to do with the monitors, but we're looking at maybe there's a better way of doing that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I want to thank the panelists and thank Liz for the question. I think it was a really good way to get to some important points. I'm being extra nice here because I'm about to be a little nasty. Dr. Goldman mentioned Continua's certification as an important part of the certification program. From its inception this is an area that we've been very worried about with Continua. We are aware of other consortia of device manufacturers that brought us certified USB, certified Bluetooth, certified Wi-Fi and there doesn't seem to be any doubt that there were some things that were essentially certified there. But the end result to the user was it only works in some engineer's point of view of working. Now that we've been through several years of USB, now that we've been through several years of other things, then it begins to work as well it is. But the underlying issue that is going on is a conflict of interest within the organization between going for the most aggressive feature set to make the product look better, and going for the feature set that can be thoroughly reviewed and tested.

The other issue is certifying the complete trip, including the things the consumer has to do to use it, whether the consumer is bioinformatics in a hospital or the consumer is a patient in the home. We don't assume that Continua can't rise to the challenge. But we think that the general direction of federal pressure on certification of standards has gone towards, if you will, a disinterested third party creating certification standards, and I think we should consider extending that to Continua if we really want to be sure of the level of certification.

Robert Jarrin – Qualcomm Incorporated – Senior Director, Government Affairs
Let me tease that apart a bit. First of all, the best thing is that I'm not an officer of Continua, but I can speak as a working group chair on the Use Case Working Group. There's one interesting benefit that comes out of the work of Continua, and that is a set of IEEE and ISO standards that are just standards like any others, widely available. But unlike others that have taken a long time to reach maturity and unlike some others that have not been implemented with reference implementations, those that have been produced through the labor of the Continua member organizations have been relatively high quality. So that's a benefit of this type of endeavor.

Another is that one of the challenges with interoperability, almost a definition, in a sense, is that one doesn't have to perform ... testing of everything, so that we can buy a USB memory stick in Target from brand X and it is highly likely to work with brand Y computer, even though they've never been physically tested. That's because an appropriate and comprehensive test suite will allow the manufacturer of the different elements in the chain to do a good job and then ultimately to certify the interoperability. That's a pretty tough thing to accomplish with standards alone.

I'm not defending. It's just not appropriate for me to defend Continua of course as an organization or a specific approach over any others. But I think that we've seen that the early days of Wi-Fi, well, it was low fi, the early days of USB sticks would crash our computers and give us the Blue Screen of Death a little too frequently and on and on. So we've all seen the early phases of implementation of things like this, and ultimately there has to be some way to achieve ... interoperability and independent certification to enable development at low cost, because you can't fill a room with every possible combination of medical devices to perform the testing. How one gets there, there's more than one way to get there and if the National Institute of Standards and Technology is the right place to do it, well, that's fine. That's wonderful. Maybe we can learn from all these other efforts and build a better approach from the health IT perspective given the importance to the nation and to our healthcare. Certainly, that would be reasonable. Did that address what you—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I agree with you completely.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
We are running over on this panel a little bit, but let me first just check again for our members who are dialed in on the phone and see if any of you have any questions.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I'm fine.

Joyce Sensmeier – HIMSS – VP of Informatics
Nothing here.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
you very much. I want to thank the panelists for your testimony and for a great discussion. We are going to take about a 40 minute break for lunch. We will start up at quarter past. Thank you.

(Lunch break)

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I did see that Mr. Parisot is not at the table. I did see him here earlier. I think we will go ahead and start and hope that he comes in by the time his turn is up. I want to welcome everyone back from the lunch break. Thank you very much. On this next panel regarding interoperability in data integration issues we have Dale Wiggins from Philips, Chuck Jaffe from HL-7, Elliott Sloane representing IHE, Charles Parisot representing GE, and John Garguilo from NIST. I hope I didn't mangle your name too badly. Good. So we'll go right ahead and start with Dale. We'll follow the same protocol of each panelist speaking in turn, followed by committee discussion.

Dale Wiggins – Philips Healthcare – Chief Technology Officer
Good afternoon. I'm Dale Wiggins from Philips Healthcare. On behalf of Philips Healthcare, I would like to thank the Clinical Operations Workgroup for the opportunity to speak today and participate in this panel. I would first like to provide some context by highlighting Philips Healthcare's unique experience in this area. Philips Healthcare is one of the world's largest manufacturers of critical care systems medical monitoring, diagnostic imaging, and home monitoring and therapeutic products. Electronic health records need to interface with virtually all of our healthcare devices, both in the hospital and in the home.

We've been developing solutions for integrating this device data for over 20 years, and together with our customers have a critical interest in reducing the difficulty and cost of establishing these interfaces. Because we provide solutions across the full ecosystem, including hospital, home, and pre-hospital emergency care, we believe interoperability must expand seamlessly beyond the walls of the hospital. To encourage this we volunteer, contribute and lead numerous workgroups in standards development organizations such as integrating healthcare enterprise, or IHE, HL-7, Continua, and DICOM.

We all know that in healthcare and data integration we face many challenges, but I am optimistic and encouraged by some of the successes that we have seen in the past two years and that we've already heard today. I'm especially excited about the work in IHE and Continua organizations. They have developed profiles that address not only message level connectivity but also semantic level integration, so the systems truly interoperate without the need for complex and expensive mapping. Continua's made similar progress in the home environment, with many certified products. I highlight IHE and Continua not only because Philips actively supports them, but more importantly because they represent organizations that are focused on quickly getting solutions to market with standards-based integration profiles instead of vendor to vendor or ad hoc solutions. Now, I'm sure that there are many that will point to the deficiencies in the current profiles, saying that they're not complete or that not enough vendors support them. Some of this is true, but I would contend that we as an industry would be wise to embrace and accelerate this start rather than to delay or start over. We must simplify condition workflow and we must reduce the cost of implementing these systems.

Now, when we talk about connecting medical devices to the patient's health record, we typically refer to it in a one-way transport. I would argue that we need to expand this conversation to include information that should be made available from the EHR as well. Many clinical problems can be best addressed in the clinical devices but they need supporting information. For example, alarm fatigue is a significant issue in hospitals today. We've shown in our research significant improvements in advanced alarm capabilities that could be developed if the monitor received information from the patient's record, such as their diagnosis or current meds. So as the workgroup looks into additional meaningful use criteria, it's

important to consider some of the value that healthcare device data can provide to the quality and effectiveness of care.

Device data can support quality measure reporting. Device data can either affirm or rule out certain quality measure compliance initiatives such as ventilator associated pneumonic bundles. My background is in system design and architecture. Healthcare systems are very complex, but not nearly as complex as the human body. Regulation often gets a bad rap, but at Philips Healthcare we like to remind ourselves every day that there's a patient at the other end of every one of our solutions. Regulation is there for a reason, and when you conduct good system design you ensure that the critical risks are accounted for. Because of this, we believe that some systems that utilize regulated device data should be subject to similar quality and safety standards as the source devices, for example, systems that use data for life critical purposes, such as ... communication, alerting, or clinical decision support. Additionally, when you take data from regulated patient care devices and use it for similar purposes such as alerting, it implies to the public that a comparable level of oversight and assurance of safety was incorporated into the development and testing of the receiving system.

Philips Healthcare looks forward to working with the Clinical Operations Workgroup as it continues to develop recommendations for the incorporation of device sourced patient information into HIT systems. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. We'll turn to Chuck Jaffe.

Charles Jaffe – HL-7 – CEO
Thanks, Jamie. I'm Chuck Jaffe. I'm the CEO of HL-7, and I wanted to thank the committee for giving us the opportunity to share some of our ideas. While most of you realize that HL-7 has been a standards development organization for more than two decades in the area of healthcare, clinical research, public health, and so on, HL-7 serves more than 95% of the healthcare systems in the U.S. It also provides health information standards for over 40 countries around the world, and the HL-7 membership represents something greater than 90% of the vendors of healthcare information systems.

Like our membership, our volunteers predicated by ANSI, represent a large swath of the healthcare community, including members from government, academia, the vendor community, as well as manufacturers, public health, and advocacy groups. Like many of the other members, I represent multiple constituencies, physicians, researchers, and I'm a patient too. Wearing these different hats provides a lot of the recognition of the complexity that our stakeholders provide, not only making a broad and complex organization but sometimes with competing interests. But since the enactment of the HITECH legislation and the establishment of meaningful use guidelines, HL-7 has focused on an enabler of the processes for information exchange.

Part of the success of that process has been our function as a collaborator, not with only the standards collaborative organization, but also with its different constituents, including Continua and IHE, CDISC and GS1, ISO and SIN, DICOM and IEEE, but also with LOINC and IHTSDO. The emerging and existing interoperable standards by and large are predicated on HL-7 v2 messages. Both the regulated and non-regulated devices are supported by many working groups within HL-7. In trying to address the barriers and enablers, I think there are three major messages that I'd like to convey. One, I believe that the greatest challenge is not technology but policy and people. Secondly, that the standards that currently exist serve more than 80% of the instances both of existing and planned exchange of data between devices and electronic health records. Some of the barriers in fact to adoption are driven by proprietary interest in technology that really support misguided business models by administrative indifferences at various levels and by the steep curve of change management.

Third, the infrastructure and project management at HL-7 are in place right now to create, accelerate, and support new standards for both innovation and for emerging devices technologies that evidence-based medicine is almost certain to drive. Although it's now in its embryonic stage, the HL-7 Fresh Look program, which I hope you hear more about, will address some of these processes with a new approach

to standards and standards development. In practical terms, however, the HL-7 Device Workgroup has provided the primary collaboration for coordination and harmonization. For example, the IHE PCD profile that enables a single common specification between vendors and the ISO IEEE semantic solution for improving semantic interoperability.

The HL-7 Conformance Workgroup has been driving toward more rigorous message profiling and strong validation testing. At Open Health Tools, for which HL-7 is the principal resource, it builds upon these technologies to support validation activities, including privacy and other tools to help enable the NIST specifications. In an ambulatory setting, HL-7 v2 messaging is really the backbone for conveying remote and home acquired device data, including, for example, the Continua IHE Win interface. Lastly, the HL-7 clinical document architecture enabled personal health monitoring and reporting now embraced by Continua. In addition, CDA supports a bridge from the ISO IEEE spec to personal health devices, both for electronic medical records as well as health information exchanges. These systems are in production today and more are planned in the next 18-month cycle.

HL-7 would like to recommend several options for adoption by the Standards Committee, which include enhancement of the prevailing terminology specifications which are indeed sparse; the encouragement by regulatory authorities and device manufacturers to enforce and comply with existing standards; to improve articulation about dated device requirements; and lastly, to help drive bidirectional communication between devices and electronic health records. As Dale pointed out, it is not simply the device which informs the electronic health record, but the ability of the electronic health record to improve device performance. Thanks for your attention.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Next, we'll turn to Elliott Sloane.

Elliot Sloane – Drexel University – Professor & Director of Health Systems Engineering
Hi. My name's Elliot Sloane and I want to thank you for allowing me to join you and provide information about medical devices in your deliberation about medical device interoperability. I have some slides to speed you through the long written testimony. I live and breathe and sit in the medical device and medical information systems space professionally. I have about three and a half decades of work with these devices, and have been steeped in these devices since the beginning of my career and at MEDIQ owned half a million devices that we rented to the country, home care and hospitals. To put that in perspective, I think the testimony from Kaiser listed 250,000 devices, so it's twice the inventory of Kaiser Permanente, by supplying 5,000 hospitals across all the device brands and models.

I'm here to speak representing IHE USA today. IHE USA is an incorporated non-profit organization that is in the state of Illinois and its role is to provide standards and be the deployment arm for IHE International, of which I'm co-chair. I want to talk about standards for medical device interoperability. In the context of the IHE patient care device domain you'll sometimes hear IHE PCD, which is a work that began in 2003 as IHE was in its sixth or seventh year of growth and had dealt with DICOM and imaging modalities and was looking at how to deal with all of the medical devices. A hospital may have some 25 to 50 imaging modalities, it may have 5,000 devices, so we're looking at how do we get data in and out of devices and into the electronic medical record reliably.

One aspect of this is the IHE PCD Rosetta Project, ably run by Dr. Paul Schluter, who is here, and you can speak with him today if you have questions about it. The whole concept of the Rosetta Project is to enable transparency across different brands of products that have different codes to represent all the different physiologic systems and symbols that they are capable of collecting. So we plagiarized from the original Rosetta Stone, creating a table of tables so that we can disclose to everyone how blood pressure, temperature, and other signals are encoded. This has also been harmonized with the National Standards for Nomenclatures so that we can move between the different manufacturers into different data sets so that we can reliably keep the clinical and scientific data correct. And here are just some simple examples of how the Rosetta system works. There are already hundreds of rows of data for just the devices we've worked with, so this in and of itself will be an ever expanding library of cross-reference terms.

Are medical device interoperability standards necessary? It's one of the questions this panel has asked. I think the answer is clearly yes, in my mind, and what I'm hearing from the other people who testified yes. It's a huge reduction in complexity and cost and it helps enhance medical care. One of the challenges that's not obvious is that interfaces present an N-squared challenge. I was just on the map here for a set of 15x15 devices and manually computed up, it's 105 interfaces to an interface, 15 devices uniquely to 15 other devices. And 500 devices is 124,000, almost 125,000 interfaces that if you have one software and one hardware interface for each side of that it's four times that, it's 600,000 interfaces. It's a daunting number. Without a national standard we're hearing from providers that are spending an enormous amount of money doing individual interfaces from product to product to product to product. It starts out easy, I just want to get this infusion pumped to that electronic record. How about the next infusion pump, how about the next pulse oximeter? Each one of those interfaces is custom written and requires, as you heard, delays to disclose on both sides what the coding is and the costs are tremendous.

With one national standard we can create a single, essentially an enterprise ... solution so that every product can directly deliver into one standard format data that can be moved anywhere, not hundreds of thousands of interfaces, 500 devices require 500 interfaces. So we have also the issue of what are the impacts of supporting these products? Connecting the products and working through the architecture of connection is something that the ONC asked us to do five years ago. We've been working on that with remote monitoring under the HITSP program, a document, IF77 and also a document TN905, that give clear guidance and is available for use today. A nice outcome of that, at the request of ONC is we've harmonized IHE PCD and continue to ... interface so that a single structure of data can move information on both sides.

The standard interface design has an enormous effect on MDDS, the FDA regulation. In principle, each interface is itself an MDDS registerable device. It moves data. That's without transforming the data. If it's actually transforming and interpreting and making some other changes, it's a medical device, I think, as far as I understand. I think that regulation is important in this space. I think the discussion the industry has to have is how to do it. MDDS is not inexpensive. QSR, three little words, Quality Systems Regulations; enormous cost. Each and every component has to be tracked, traced, traceable, and recall liability. There's a lot of issues that come with this and a lot of six figure employees to do this work, and in our hospitals around the country 80% of them are small bed hospitals, is probably impossible to do. MDDS plus non-standardized interfaces I think creates an enormous number of overwhelming numbers to work with in terms of how we can get products from point to point and how we can do the software to manage the cost.

Some solutions: What we have in IHE PCD are some well-developed solutions. Those are in the vital signs data acquisition and transferred to electronic medical records, acute care device data acquisition and home and wellness integration with Continua Health Alliance products. Strong progress is being made with alarm and alert communication and transfer between devices in EMRs, real time wave port data straining to move the actual data in its raw form, patient device information binding. Then in Continua development right now is on integration with the ICE and the medical device plug-and-play areas that you heard Dr. Goldman talk about, device-device integration and communications management.

Our recommendations and request for this committee, this subcommittee, this taskforce to do is to add ... to meaningful use stage two and stage three, especially with respect to chronic diseases and to practice automation. If the IHE PCD profiles and the Continua profiles are put to work as they were designated in the IF77, we could be moving data fairly quickly. Products are on the market. Quite a few companies already have this architecture developed. Then item two, add IHE PCD to the automated acute care data capture for meaningful use stage three. Let's begin the process. It's a journey. It won't happen overnight. But it is something we're able to do. This commitment by ONC will allows us to reduce the overall costs, improve the effectiveness of care and patient safety. All of IHE is run by volunteers. It is staffed by people from almost every kind of hospital, every kind of clinical profession, and every kind of manufacturer. What we want to do is put the country's money to work in patient care and not in dealing with artifacts or administrative technologies that don't forward the cause. Thanks for allowing me to offer my comments. I appreciate being invited today.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Next, we have Charles Parisot.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
Good afternoon. I'm Charles Parisot, the Interoperability and Standards Working Group Chair from the EHR Association. I work for GE Healthcare, but I am not representing the viewpoints specific to GE, but those of the EHR vendor community. The EHR Association is a strong supporter of the HITECH Act and of the work that the HIT Standards Committee has done and will continue to do; we are convinced. Our experience as EHR vendors with healthcare and health devices and their interoperability has evolved dramatically over the past few years. We have grown from a limited number of projects in a few large institutions to an increased demand in users' expectations, now covering the broader spectrum of inpatient facilities and ambulatory facilities. This demand is now clearly present in the ambulatory space, and this is new and we don't want to disappoint and not meet that demand that demands a really standardized, simple to deploy solution.

The first point is that we would like to clarify a point of confusion that I think has been kept this morning, although discussed, Wes has asked a few questions around this, are we talking about bringing medical data into the EHR**,** or are we talking about connecting medical devices? We believe that those are two topics of conversations that are related but shall not be confused because in between those two there is a little something in the middle that we have a hard time discussing. Some call it middleware. Some call it an intermediary. Some call it a gateway. Some call it a nursing station. Some call it a health and wellness management system, many, many, things, but there has been a realization that IHE made four years ago in looking at the device environment, is there is an intermediary between the device and the EHR. Although I have heard this morning that some people would wish this intermediary to disappear, we think in the EHR vendor association that the reason this intermediary is so multifaceted is that it is absolutely necessary, even if we standardize everything on both sides we will need ... an intermediary and thinking we're going to remove it is an illusion.

There are issues with custom devices, if you want to deploy local devices and you don't have an aggregator or a gateway in the middle, this is impossible. If you want to deploy a device at home, this is impossible. You need a hub in the home to communicate on the outside, and all of the witnesses we've heard this morning have such a device in place. I think they're asking for reducing the cost of that device and the way to use it. Removing it, we believe, would actually be pulling us backward, so what we would like to do from then on is to discuss what are the interoperability standards that are the most germane to the discussion, which is between the intermediary and the EHR. We would like to make sure that the major changes that have happened over the last six months are understood by this committee. Because we believe that the description of the world we've had this morning is about to undergo a major change of paradigm. This is coming from two sides.

The first side is an amazing convergence that I want to stress. We've heard about it, but I want to stress it, is interoperability of home and wellness devices and interoperability of in organization, hospital, whatever you want to call it, devices. Those are very different in terms of quality, in terms of processes, in terms of tracking the data. However, the interoperability problem is the same. This realization came about, as was mentioned by a number of other folks on this panel, and resulted in Continua and IHE sitting down together. IHE had started from the inpatient world and was moving into the home world. Continua was starting from the home world and was saying how do I connect the data to the healthcare system? Guess what? Those two organizations have converged. We've looked at the standards and we have a single agreed way to go from the intermediary to the EHR, or to the intermediary to the PHR. That is an absolute game changer, because now we have an economy of scale of a single standard profile specification that we can build both in the home space and in the clinical device space.

Our recommendation there is to say that these are the standards that this committee should focus on and this is essentially a ... profile by an IHE standard called DEC, or sometimes called PCD01 that defined a subset of ... very precise to convey that clinical data, and it supports today over 300 devices. Five hundred pieces of data elements that are completely specified up to the terminology of every value, every

measure, everything is fully specified so that people that are bringing this data in the EMR know precisely what to do. We know now that the tools and the testing tools that are developed, and IHE is working with NIST on this, those test tools have now reached a good level of maturity. We think that this is plenty sufficient and the recent testing that has happened, as reported by ..., where we had a significant number of device vendors and EHR vendors. We did mix and match all of those with all of those actually worked, this was a success and that made the EHR vendor association say, hey, we now have reached a critical point, we need to leverage this.

So where should we go, take 300 or so devices for which we have all of the data description, that would not be reasonable for meaningful use stage two or stage three. So I've heard this morning, and I would like to make EHRA is supporting this, let's pick a few, Wes said three, four, five, a few critical devices that have the biggest bang for the buck, and let's focus on those, let's deploy those, and let's have the meaningful use process proceed on those. The security standards are in place and profiled to do that. What we recommend is to include those three to five key devices for stage three. Although I have described a very encouraging scene, we need to realize that broadening the range of product, proving all of the implementation, that is going to take two years. We now have vendors that have announced products and enough EHR vendors and device vendors that we think this is going to happen. It's rolling now, however, if we want this to be meaningful use we think stage three is the right place to do that while it needs to be announced in stage two and the standards selected at that time. Thank you very much for your attention.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Now we'll move to John.

John Garguilo – NIST – Computer Scientist
Thank you. John Garguilo, I'm a Computer Scientist from NIST, and today I'm here as a black box; I only see what goes into the box and what comes out of the box. At the U.S. Department of Commerce National Institute of Standards and Technology, researchers are collaborating with medical device experts to facilitate the development and adoption of standards for medical device communications throughout the healthcare enterprise as well as integrating information into the electronic health record. We have developed software test tools and a modeling application, which provides several important capabilities leading toward device interoperability, much of which Charles has just mentioned

Conformance testing is a key step leading to, although not guaranteeing, interoperability. Sparked by involvement over the past several years of working with medical device domain experts and vendors who participate in SDOs, or Standards Development Organizations, an approach to identify testable assertions derived from standards and constrained by important use cases was developed and continues to evolve. Such medical device and health-related standards such as HL-7, as Charles mentioned, ISO IEEE 11073, both the personal health and point of care data communication standards or parts of those standards, and the ASTM F2761-2009, commonly referred to as ICE.

The black box messaging test approach addresses how we define and get to a level of rigor that improves if not, dare I say, ultimately assures, given no optionality, correct data exchange. In particular, verifying that physiological information derived and communicated from a source medical device, for example, an infusion pump or a health information system, to a medical device such as a patient monitor or health information system that consumes or makes use of the data is both syntactically and semantically correct. In other words, the structure of information exchanged within the healthcare system is compliant to a defined specification and information meaning conveyed and interpreted by the consumer is exactly the same as intended by the source.

Unfortunately, though, this ultimate assurance can only be a reality given more than technological solutions. The commitment to and consistent use of industry standards is essential. To achieve commitment and consistent use, buy-in of key stakeholders is critical, perhaps first and foremost by the leadership, as well as information technology, clinical engineers, and users. Because the lead time for medical devices and systems is lengthy, as we heard this morning, vendors must become committed and

actively involved in the near term, and users must begin to budget for and specify interoperable devices. But since I'm from NIST, let me get back to and stick with what I know best, the technical side of things.

The reality that medical devices need to communicate with tens, if not hundreds, of other devices of varying makes, models, and modalities has large market and substantial healthcare implications. Acute point of care settings such as a hospital's intensive care unit, a patient's bedside, or personal telehealth location, require each class of medical device to use the same terminology and data organization to seamlessly and reliably communicate physiological data. Healthcare communication standards that address plug-and-play medical device interoperability are critical. While providing the groundwork to enable device communications, standards are developed in an open-ended manner, and for very good reason. It is my contention, through experience in software testing, that only until standards and defined specifications are constrained to create profiles, that the desired guarantee of syntactic and semantic correctness can even begin to be achieved.

Conformance test methodologies are being employed by NIST via software test tools to help get closer to that guarantee. These tools are publicly available and being used by the medical device industry to ensure that critical devices correctly implement the medical device standards. Consortia of medical device vendors have come together, and more are coming, to use such test methodologies to successfully meet a level of compliance to standards sufficient to achieve truly efficient interoperability. Correct implementation of standards lead to effective exchange of critical physiologic data derived from the patient at the device and exchanged throughout the healthcare enterprise and backwards, as we've heard several say today, for evidentiary data.

As more and more devices are able to achieve plug-and-play capabilities, healthcare givers are empowered to focus more on the patient, diagnosis, and treatment and less on the devices. The ability to reliably and effectively integrate data from a broad range of point of care devices will ultimately lead to a reduction in medical errors and associated loss of life. From the buyer's perspective, resources providing procurement guidance and a level of assurance of device interoperability is an essential need. To enable device interoperability more rapidly, particularly from the health information technology side, identification of key use cases driving efforts to pilot and prototype medical device systems should be encouraged. In fact, several efforts are underway leading to interoperable medical device products showing up in the market, many of which Elliot highlighted in his presentation. Such work must be performed in a cross-industry, consensus-based manner, with buy-in of appropriate and committed resources. Implementation guides and conformance profiles are key ingredients to articulate meaningful use requirements to device manufacturers and test system developers respectively. Additionally, articulation and guidance of such requirements lead to evaluation criteria necessary for users to make informed procurements.

Medical Device conformance leading to interoperability, based on standards and to a finer level constrained profiles with clearly and unambiguously defined assertions, will not happen overnight. Such work should be iterative in nature and provide feedback to the SDOs and to establish meaningful criteria addressing key needs in our healthcare system of systems. With physiologic data primarily being derived at the medical device a process driven by meaningful use criteria cannot be put off to the future and must be identified today. Criteria called out specifically for devices to meet defined meaningful use priority areas should be established as soon as possible. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great, thank you very much. Before we now turn to questions from the group here, let me go back and check in for those on the phone. We do have some members, again, on the phone. I think we still have Joyce and Don and Dixie. Let me first turn to you and ask if you have any questions on the phone?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I do. This has been a really interesting, well the whole day has been incredibly interesting. Several presenters throughout the day have mentioned the need to capture provenance of clinical information that's captured by home devices, acknowledging that there is a difference in its integrity, if you will, and some are loading it into a separate repository, and others are labeling it as from home devices. Elliot recommended including the remote monitoring in meaningful use stage two and three, both of which are

likely to include interactions between EHRs and PHRs. So, all of this gave me a question about exactly what we're talking about with respect to integration of home devices. So, recognizing this need to somehow separately categorize data that are captured by home devices, what occurred to me is that maybe these data should be uploaded to a PHR as Microsoft ... develop and Google Health envisions, and then made available to EHRs the same as any other patient sourced PHR data. So my question is, with respect to these home devices, should we be thinking about standards for uploading these data to PHRs or EHRs?

Elliot Sloane – Drexel University – Professor & Director of Health Systems Engineering
First of all, we have designed in the Continua and IHE interface a bit that identifies non-FDA regulated devices. Versus regulated medical device data, so that you can distinguish what may be called a consumer product that might be purchased at a Costco or a Wal-Mart from a product manufactured, let's say, by Philips as a medical device that's regulated as a 510(k) approved medical device. So we do have a way to segregate that data and put it in a PHR or put in the EMR or EHR environment. The whole question of where data belongs, who owns it, which record it goes in is a large question that I'm not even going to try to bit off, and keeping those in sync is a large question, but I assure you we can separate the two kinds of data.

Charles Jaffe – HL-7 – CEO
Dixie, I have a slightly different perspective on this. While I have no concerns about separating regulated and non-regulated devices, I think we can put data from a home care device into an electronic medical record and just keep it in a separate section. In an EMR we identify subjective data and patient history in one portion of the EMR and we don't commingle that data with other sources of information. I can envision bringing home device data into the EMR in such a location that it's recognized as not being professionally sourced.

M
If I can add further to that, one point of clarification is that there's a commonality, regardless of whether it's PHR or EHR, from the way that that information is carried through a message. For example, in HL-7 some key differentiators are how you constrain that message to meet a particular profile or maybe class of device or a make or model of that particular device and also the set of terminology is very important to be defined for what device you're talking about. So if it's a pulse oximeter versus a ventilator in the critical care scenario, you have a well-defined value set of that nomenclature and there's also some associated information with that device terminology that can be used, for example, units of measurement, the body site, some enumerations. So it's very important to keep in mind that the actual carrier is common across, for example, Continua and IHE using HL-7 version 2.6 messaging.

M
There's one other clarification, which is that the ISO ...11073 tags for the personal health devices are different than the general clinical environment. They're simplified. A home device for blood pressure is only going to be expected to have systolic and diastolic, and that's the only values you're going to expect from it. You're not expecting, perhaps, indwelling catheters or other sites. So it has been constrained, made more simple, so it is visible at all times what is that data, where did it come from, and where is it sourced?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Do we have any other questions on the phone from Joyce or Don or Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I'd like to reply, if you don't mind to what Elliot said. To me whether it's regulated or not the key issue is where it's sourced.

Elliot Sloane – Drexel University – Professor & Director of Health Systems Engineering
Okay, well there are two parts of that, Dixie. One part is where it's sourced, but another part is, by law a medical device needs to be kept in conformance with original specifications. Under Medicare, if a device is rented to a home setting it is required to be kept operational, calibrated according to manufacturer or

some other industry specifications, and that wouldn't necessarily be the case for a consumer product. So this is a somewhat larger technical area and I think we all agree that we have to keep our eye on it clearly and understand where the data's going, how we're using it, and making sure that the clinicians know what the data is, what it represents.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, I agree. Thank you very much, all of you.

Joyce Sensmeier – HIMSS – VP of Informatics
Jamie, thanks for asking. I don't have any questions for the panelists.

Don Bechtel – Siemens Medical – IT Architect, Standards & Regulatory Mgr.
Me neither, not at this time.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, good. I will take the prerogative to ask this panel actually the same question that Wes asked another panel earlier regarding the actual implementation experience of some of the standards that you're talking about. So I think in particular we heard about some of the success of coming up with a single specification from intermediary devices to feed data into EHRs. Can you cite particular programs that have been in place that have implemented this, and can you provide us with some reference materials, perhaps off line, that would support that?

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
I would like to provide two answers to this. The first one is the stable specification that is now agreed by Continua and IHE, that PCD01 with the ... terms and terminology and definition of data elements has been completed over the last summer. We have moved to NIST, growing their tools, and we have gone through the first phase of early implementation testing in January. That phase of implementation testing was very positive. The device vendors and the EHR vendors have said, that's good, we've reached a level where we can play between multiple intermediaries and multiple EHRs and this is working. The credibility of a specification has been reached, the credibility of a tool has been reached, and what we need now is to move this, as Wes correctly stated this morning, into a production environment.

If you read Elliot's testimony in the back, there are already some vendors that have listed and announced their products. That list is going to grow, especially on the device intermediary side, where there are some regulatory constraints and you will see some competitors that are missing, simply why, because from a regulatory standpoint they cannot announce a product that has not undergone the regulatory process. But all indications from those folks is to say, yes, this is mature, this is going to ship. So what we said in the EHR association is our assessment on the device side is shipping within a year a significant number across a rather large set of vendors, device, and intermediary systems because sometimes ... the same vendor, sometimes it's a different vendor.

On the EHR side, we had been doing HL-7 2.x interfacing in the wilderness for the past ten years around device things. I think the last time I looked at some of our EMR and gateway stuff we have over 100 to 120 flavors of that thing. We're adding one more flavor, which happens to be the standardized one, ... On the EHR side, and speaking as the EHR vendor Association, the EHR vendors are saying, hey, all of us have been connecting out of the mess that we have today, doing it with ... PCD and Rosetta Stone is not a problem. We do that every day and it takes the time it takes. We can even make it faster, because we know the specs in advance of discussing with our customers. What I do expect is that the EHR will come out quite early in the game and we're going to see lagging for the reason we explained this morning, the device in the intermediary side to ....

M
Maybe if I can add another point to that. I'm actually very encouraged to hear that from the EHR Association. We actually do support a release product that supports IHE today and the PCD profile that we've mentioned here. I think we are to the point where we can start to see the device level adoption. To answer your specific question, I think where you do see a lot of success is in the radiology side. And if

you go to the IHE Web site there is a separate link that is a link to success stories. It's somewhat dated. I hope Elliot can address it, because it says "To be Updated" on it. I think the impetus now is for EHRs, device vendors like ourselves, to provide incentives and easy implementation guides, if you will, to providers so that it is very effectively and efficiently rolled out.

Elliot Sloane – Drexel University – Professor & Director of Health Systems Engineering
I have another ... response. Virtually every technology that would be used in home care and in vital signs data capture has been handled and well tested with a variety of devices and EMR companies. The testing of the products goes back to 2006 of the interfaces and the demonstration of those with NIST actually as part of the referee for the usability of those interfaces. I think the odd thing that happened is at the end of 2009 when the stage one meaningful use criteria were released, it didn't include any remote monitoring and everyone in the device field took a deep breath and only is now really prepared to come to the market and get this addressed completely. It was a pregnant pause, if you will.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. I see Wes' card is up.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm just a bit confused about what we're talking about here. We have talked today about the home devices. We talked about instruments that are used in the hospital or in a clinic or something like that. I was not aware that we were talking about radiology. Are there radiological instruments that are hooked up other than as image sources to ... and as information sources to radiology information systems?

M
My point in terms of drawing the analogy there was the adoption of the IHE profiles. If you look at success stories that have utilized what we're talking about with IHE my point was that that is where there aren't very concrete customer success stories.

M
Also, I should say that some of the infrastructure tools related to consistent time go back five and six and seven years. The consistent time capability in IHE for the DICOM images was discussed in 2004, 2005, and the standard release in 2006, so some of the primitives that are used for other. Those are medical devices of course, even the x-ray system, so some of the primitives that have dealt with regulatory concerns and accuracy, fidelity of medical records have preceded the work that medical devices , what we're talking about medical devices, portable physiologic monitoring, infusion pump kinds of devices. Then if you extend it further to what Julian Goldman was talking about, control of surgical devices, x-ray equipment, ventilators, that's even going beyond real time actual control. So it's a spectrum, you're right. You're sensing a spectrum. It is a spectrum.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yeah, thanks. So, we have in place a group of—and I get a little confused here—PCD, there's several IHE terms and I just don't want to use the wrong term. PCD is what, what would you call it?

M
Patient care devices.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, but is it a profile?

M
They are profiles, they are integration profiles.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

All right, okay.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
Wait, there are two terms that IT keeps on switching back and forth. The profile is officially called Device Enterprise Communication, DEC. This DEC profile has a transaction that is labeled PCD 01 that allows Device to import data and people are toggling between the two because it happens to be in a bi-unical relationship except that the source needs to be time synchronized, which it's more than that, so actually the official term should be DEC.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
That's good, Charles. It helps keep analysts at Gartner in business. Just to summarize what I think I heard, Continua has the point where it has a few pilot implementations in the field and being evaluated. We learned, if we didn't previously understand, the new set of criteria related to ease of use for the patient today and we have a chance now to look at that. If I understand right, PCD is about the complementary capability—or DEC, is about the complementary capability, which is for instruments in…, no that's not right, okay.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
This is one thing that I hope I had made clear, but thank you for reminding me that it was not the case. If we look at a device, we go from a device to an intermediary. We go from an intermediary to an EHR, PHR or health management system that is doing something with the device with the device data. In the Continua model, the intermediary is a home hub, is a set dub box, is a cell phone, is a little bit program running on your PC. The device to intermediary is what Continua has defined so that you can buy the device, and buy the intermediary, your home box or home gateway from different entities. When you move from the home to a system that is going to actually use a device data, this middle interface is called in Continua the WAN interface. In IT, it's called the DEC profile. Those two are using exactly the same standards, the same profile, the same security, the same subset, completely aligned.

Of course, the payload, defined in IT by the Rosetta Terminology, the Continua will use certain rows that are related to home health devices, where in the hospital you would use infusion pump and clinical devices. So, what is important is when we look at bringing data into the EHR is that it is the intermediary to EHR interface, or what Continua calls WAN or IT calls DEC, the same thing. That is, I think, the primary topic of this hearing from a how do we bring data inside meaningful use, so in the record system.

In the home setting, patients, because they are buyers of devices, need absolutely that standardized interface device to intermediary. In the clinical setting that interface is not standardized or not has not been successfully standardized. We could have an interesting discussion as to why this, and this is a discussion we started with iTripoli n73, we tried to do this and that didn't get any uptake. One of the reasons for this is because, number one, the HR vendors want to see an intermediary. The intermediary and those devices are both regulated entities. Opening that communication and making it standard plug and play is opening a regulatory problem, difficult, challenge that has been a big question mark in the industry where the vendors don't know where to go, some of the users don't know where to go and we've been watching this and nothing has happened into more standardization there. The message of EHR is to say let's not worry about this in the clinical setting, because in the clinical setting it is the intermediary to EHR interface that is the critical one to standardize with DEC and WAN for Continua. Is it a little clearer? It would be great to have a drawing because it becomes quite clear when you draw a picture.

M
Here's my drawing, okay. You've got an instrument, you've got an intermediary, you've got an EHR, Continua talks about the span, but you have to cut it this way because it's about home devices. IHE talks about intermediary to EHR, but it's broad vertically because it covers all kinds of devices.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
You are correct.

M

And, in fact, for home care the lion's share of homecare are with regulated medical devices. Those are the products used every day, apnea monitors, pulse oximeters, ventilators.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
You mean, you said home, clinical.

M
I'm sorry, clinical general medical devices from the portfolio of hospital care of what's used every day.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, we have different use cases or different realms of care that apply as well. What I understand is that for the—I'm just going to say PCD, I'm sorry, for PCD we are to the point now where we could begin to get some actual feedback on use.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
PCD plus Rosetta Stone; you need the terminology on top.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
The reason you're optimistic about that is because there are no devices there in that loop. That is, nobody has to manufacture a new device. It's all software that's involved. Okay, thanks.

M
We actually tackled the tough stuff first, the anesthesia machines, the ventilators, the infusion devices, in terms of trying to see could we capture those and make that data move and, of course, the physiologic monitoring.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Just to be clear, an anesthesia machine, what's the intermediary?

M
There's typically an anesthesia information system that is gathering logging that information.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
And for telemeter e-bed, it would be the nursing unit that's displayed.

M
Correct.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
And for bedside vital signs it would be?

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
It's either a nursing station as well where there is a nurse that oversees a number of beds.

M
Or it can be an adapter for an EMR system. We have Epic and Cerner adapters that have been written that can receive the data.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
Sometimes this is a black box intermediary; sometimes it's an intermediary with an application and there are a whole bunch of combinations depending on your deployment model and I think Julian this morning explained that here we need flexibility. But our take away is that in 95% of the cases an intermediary is needed for other reason than interoperability, for device cost, for concentration. People don't want to have 5,000 interfaces to 5,000 devices to their EHR, they want a few concentrated.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

I don't think we need to go on about that. I think it's a thing people have to recognize as they read IHE specs is that just because there is a logical thing there, that doesn't mean there's necessarily a physical box there.

M
That's also the domain the middleware companies are serving and more and more companies are providing adapters, boxes, systems, gateways.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Let me just make clear my view on middleware. It's awful stuff. We should never use it unless we absolutely have to and we're always going to have to.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
To confirm this, what the HR vendors say, the reason why we have some of those boxes and we are putting them on the market is because we have to. We are stuck with that. With that PCD interface, that problem can become out of the EHR problem and it becomes a device deployment problem. We think at that time it's putting the right responsibility on the right side, because you have to deal with it with your install base of devices, a different kind of device, a kind of nursing application that's needed. That needs to be owned by the bioengineering department and there is a strategy here in its own right that needs to be disconnected from the EHR strategy in the institution.

M
Wes, the MDDS regulations throw a new wrinkle into things because if the PCD portion, up to the DEC, the PCD that communication is owned by the medical device manufacturer. That's one thing. It's all within its regulatory portfolio. I it is custom built by the hospital as Intermountain is doing, then they are going to have to register as a medical device manufacturer and support all those interfaces. That might be a proper place for a period of time for a middleware company to be a regulated medical device and do this work responsibly. So, there are different flavors. Ideally in a world, all of these things will plug and play and work together, but we as was pointed in the last session Wi-Fi didn't happen that quickly.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
At the risk of redundantly repeating myself, again, I think that happens through years of evolutions of versions, it doesn't happen by creating a standard thing.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Now, I do want to recognize Nancy, but I've actually been holding a question of my own for some time now. This is completely a change of topic and so we may come back to this general topic, but I did want to have a chance to ask this panel to think in a different direction. This actually came from something in the written testimony of Dr. Jaffe, where you talked about patient health literacy with regard to devices as one of the key needed changes for success in interoperability of devices with electronic health records to promote health and wellness and improve outcome. Can you expand on that a little bit, please?

Charles Jaffe – HL-7 – CEO
Sure. In a broader sense, we are looking at alternatives to the current healthcare payment in management paradigm with medical home model, accountable care organizations, and so forth and so on. The component of that equation that we always leave out is the patient; I'll call them patients, not consumers. I think before we're going to be successful in improving any of this, we have focused upon improved physician adherence, getting physicians to comply with and adhere to clinical guidelines, either by decision support or other means, but we constantly miss the fact that part of the health delivery problem is the patient. So I believe that with devices and with other simpler problems improving the patient's understanding of what they're doing and why they're doing it and how they're doing it would make an enormous change in the quality of care.

I don't think we have a system and I don't think that the national coordinators focused on this sufficiently, but I think it's a real challenge and an important problem. If you look at women with adjuvant

chemotherapy for breast cancer, when the drug is free only two out of three actually put it in their mouth. I find that inconceivable. The same is true with HIV AIDS taking their free medications and I think part of it is the lack of healthcare literacy. So I added this as another example of things that we must do before any of these technologies matter and that is, tackling the human factors portion.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right. Thank you very much. So, now let me turn back to Nancy Orvis, please.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
That was a very interesting statement. I could ask questions about that, but my original point was to follow on with Wes' questions about the patient care device and interfaces and the fact that I wanted to clarify. Are you saying that there is the possibility here in the next couple of years that there would be a coherent way that bioengineering could plan the deployment of medical devices with a very simple plan? My question comes from the fact that the DoD as an institution works in many environments.

I have 59 inpatient hospitals, I have 102 sites and, as you mentioned, things like anesthesia devices that work in an outpatient have been a humongous challenge to deploy because it basically is every site is unique on how to install that and hook that up. There's probably very little dollar savings on having done the initial purchase when you're trying to realize that it's taking a couple of years to figure out how to get security clearance and to hit them up and depending on each system. So, can you clarify, again, to me what you see as the to be vision that's going to help.

Elliot Maxwell – ONC – Expert Contractor for Health IT
I'll try and I don't want to oversell this. This is not a trivial undertaking and there's a lot of legacy technology out there, but let's take infusion pumps. We have three of the largest infusion pump companies in the country who have already developed interfaces and at the showcase, the HIMSS interoperability showcase, were able to demonstrate drug-drug interaction checking between the three different pumps as if those three pumps were at the patient's bedside.

If a biomedical engineer had that to choose from as a commercial suite of products, it would make their life a lot easier. In the last five years, we've had all three of the anesthesia company vendor's products at the showcase. When I say three, there really were two until this year Mindray introduced a new product manufactured in China, which has the IHEPCD interface as its standard interface. So, I don't want to oversell this as being simple, but makes it much, much easier if a clinical engineering department. The CIO can specify IHE PCD compatibility as their preferred interface for each product they purchase going forward, and that is made simpler if ONC puts it on the roadmap for medical devices over the next four to five years.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
I want to correct you, if I may. The challenge we have is I wholeheartedly with what Elliot said. However, looking at it from an EHR side I would like to make sure we distinguish device connection from device data interoperability with EHR. There may be a system in the middle. So, yes, if your problem is to get anesthesia machine data inside your EHR, then we are seeing the solution right there and we think it is a solution, which is reliable, not immediately available, but already on the road.

Now, an anesthesia machine today may not support that interface. However, what we believe is that having a gateway function, either added to the anesthesia machine or part of the anesthesia information system or a third party middleware with, we wish it would not exist. But maybe that's what you're going to need because that's what you have in your install base and then going to the standard on the way to your EHR. That's where there is certainty; thinking that we are going to standardize in the inpatient setting the actual interfaces to the hundreds of devices that are used in the inpatient onto that gateway, like Continua has done for consumer device, I would say that remains a question mark. However, the step for you to get to the standard is going to be small and probably supported by your anesthesia machine vendor or by an associated vendor.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Let me ask a follow-up and then Nancy has a follow-up.

M
You're still on your original question.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I'm still partially on my original question.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
I tried to clarify, but apparently I'm confusing you.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
No, I think that's good, but I think the other piece in there is data terminology is in some of these machines and their proprietary terminologies now.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
If you look in IT, at the Rosetta Stone, the profile is called RTM, Rosetta Stone Terminology Mapping. Why is there a mapping exercise? Because the mapping exercise to a standardized terminology that is actually coming from iTripoli, that has been completely profiled for over 300 devices, including infusion pump and most of the stuff you have in your hospitals. When IT is taking those terms and standardizing them the game is to take actual devices done by actual vendors and to actually include the terminology from those vendors who are ready to release it to make sure that we know how to do the mapping. So, the IT exercise is not only to have a standardized terminology on the way to the EHR, but to make sure that the mapping from the standard terminology to existing machines is doable and is proven. It's only when this is done with three or four different devices from different manufacturers that those terminologies get adopted and become part of the RTM.

Now, please the mapping is here because we want to be business critical. EHR vendors love that because we are saying aha; therefore the mapping into the Rosetta Stone terminology of actual device is something, which is doable. It has been proven in the IT spec, therefore we believe in it and we're willing to bring those terminologies in as standardized terminology.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
That's great. Thank you.

Elliot Maxwell – ONC – Expert Contractor for Health IT
Can I just add one last point to that? Then you can test it.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
Yes, thank you.

Elliot Maxwell – ONC – Expert Contractor for Health IT
Because you have a common terminology set and you have associated values with that term that start to get at your semantics of what was meant by the sender, what was interpreted by the receiver and whoever is testing that can look at those fields and use those value sets in a very consistent way regardless of what device or what intermediary is going to what EHR and vice versa.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Those will need to be adopted, too, along with if this was a recommended specification, the testing.

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
Of course, that those tools are the ones. If you want to bring an intermediary and the associated device to an IT connector thumb, you must pass those tests first. Every time his tool sees something that says observation from an infusion pump, immediately he starts on checking that the terms that are used are on the list, the units that are used are on the list, so all of the terminology expression and the detail is per the spec. If it is not, flag alert; you're sending something that you claim is coming from an infusion pump, but

it's something else. You're using wild codes and units, I'm not sure what it is. You don't pass. Fix it. You cannot come to the connector thumb.

M
Jamie, I just wanted to comment that as we wrap up we have a bit of a disconnection here between the statements from users this morning that they were very concerned about the cost of deploying instruments and the coverage. I think a lot of the work that's been described, significantly this terminology mapping that we just heard about is important, but we need to decide what is the economic benefit that we're going after and focus our work on that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Any other questions from our members on the phone? Then I think we're at time for this panel. I want to thank you very much for an excellent, robust discussion, great presentations. Thank you all very much. We'll take just a couple of minutes to switch to the next panel.

Thank you all very much we are ready to begin our next panel on data accuracy and integrity. I want to check, I believe we have Marlene Haddad on the phone. So, Marlene, you will go third in our order here in terms of presenting your verbal comments, your oral comments and so once again we'll go through the panel. We'll start with Tim Escher, go on to John Zaleski, Marlene on the phone and then Karen Thomas here and then we'll follow that by committee discussion.

Without further ado, I'll turn it over to Tim to get us started.

Tim Escher – Epic – Software Developer and System Architecture Engineer
Good afternoon, my name is Tim Escher. I'm a Software Developer and System Architecture Engineer for Epic. My background includes medical data interfaces, especially HL-7, device interfaces and system design. I've worked for Epic for 21 years in various technical capacities, most recently as the division manager for our foundations database and reporting data warehouse group.

One of the disadvantages of going late in the day is that some of the points that I make may have been beaten into the ground already, but here goes anyway. I'm not here to represent Epic, but rather as a member of the EHR Vendor Association and, in generally, based on our experience in implementing device interfaces with our EHR. I very much appreciate the opportunity to testify today, especially with a distinguished group such as this. With regard to accuracy and integrity of data interface from devices into the EHR, the environment being considered is currently the largest differentiator that we see: clinical, inpatient or ambulatory versus home monitoring. Our experience recently is that device interfacing in the clinical environment is a fairly mature technology. There are well-known standards available and a viable of middleware devices that make device interfaces fairly straightforward and technically reliable. The implementation of the interfaces can be a project management challenge, however,

The project usually requires coordination of several inside and outside groups, including device vendors, EHR vendors, middleware vendors, facility and networking departments, biomedical departments and clinical analysts. It can also be a significant testing effort since every installation needs to be tested with all possible parameters to ensure proper mapping and storage. The implementation timeline, therefore, can be several months in length. Once a project is complete, however, our experience has shown that the collection of device data, whether metadata about the devices or the device metrics themselves is reliable, well trusted and understood by the clinical personnel. It is imperative to ensure that there are reliable methods to associate the correct device where the patient is actually monitoring. Reliable ADT and bar coding processes have reduced patient identification risks in the inpatient environment. In the ambulatory setting patient identification can be reliable as long as the devices are matched through either integration with the EHR front end or through location data from the connection to the device.

Our recommendation for meaningful use requirements for device interfaces in the clinical environment is that stage three is the logical place to consider them. Since the technology is fairly mature, adoption by clinical organizations is not so much a technical hurdle as an implementation one, possible requiring some costly facility changes, such as rewiring or construction. The maturity of the EHR interfacing

standards and profiles, for example the IHE, PCD and RTM that were just talked about are now available for deployment and will even further facilitate adoption. Therefore, once organizations have finished implementing stage three requirements, including device interface requirements in the clinical environment of part of stage three seems reasonable.

The home environment is significantly different from the clinical setting relative to accuracy, integrity and adoption. In Epic's experience, very few organizations have interfaced home monitoring equipment to their EHR, either directly through a middleware system or service. In our case only a handful of organizations have implemented, mostly only as pilots. It is a rapidly evolving environment with changes in available Internet access and bandwidth, changes in mobile technology and the expectations of patients. Although we appreciate the convergence between integrating the healthcare enterprise, IHE and the Continua Health Alliance choice of standards in the alignment of profiles, issues such as patient education, correct usage of the devices and understanding an automation or not of the upload process combined to create a lower level of data integrity and accuracy and a corresponding lower expectation and trust on the part of the clinician.

Patients who most need home monitoring are often the least prepared to deal with today's technology challenges in the home. If you ever tried to connect a Slingbox for your home network for Internet access you probably agree. We think that the secret to success in home monitoring is likely to be something such as 3G and 4G type network support actually built into the devices with simple ways to associate these devices with the patient identification and confirmation that the device is actually being used on the patient of interest rather than on another family member.

Because of these issues, we believe it will take time for the industry, not just healthcare IT, but also telecom and device manufacturers to work out the reliability, accuracy and usability issues inherent in any new technology area. Think about how much change has occurred since the iPhone was introduced in 2007 and try to predict the environment in the next three years. Although we think home monitoring can enhance care and outcomes, for now we should leave adoption of these devices and programs to a normal course of progression so that they evolve in sustainable patterns. Therefore, our recommendation is that home monitoring interfaces into the EHR not be included in stage two and then to re-evaluate the state of the technology before deciding on stage three.

In conclusion, to recap our recommendations in the clinical setting we feel that some aspect of device interfacing in the stage three requirements is reasonable given the technology maturity, but allowing for the implementation challenges that still exist. In the home setting our recommendation is that no stage two requirements be considered and to re-evaluate prior to stage three. Thank you for your time and consideration and we look forward to working with the HHS and HIT Standards and Policy Committees in this important area.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
We'll turn next to John Zaleski.

John Zaleski – Nuvon – CTO and Vice President, Clinical Applications
My name is John Zaleski and I am the CTO and VP of Clinical Applications at Nuvon, Incorporated, which is a biomedical device network overlay intermediary manufacturer. The remarks I make here today are not meant to be construed as official policy position of my employer, but are based on my accumulated experience over the course of nearly 20 years in the field. My experience with patient care devices extends back nearly 20 years. I hold five patents and have authored two books on the subject of device interoperability to electronic medical records.

Starting out during my doctoral work at the University of Pennsylvania Medical Center I conducted clinical trials involving patients who had undergone coronary bypass weaning and had developed methods and clinical guidelines associated with these patients. It was during those embryonic days that it became obvious to me that in addition to the interoperability the data integrity and accuracy are truly necessary. Dense and complete measurements are the basis for high fidelity modeling and accurate predictions associated with clinical guidelines and clinical decision-making. So, it is dependent not just on having rich

data, accessible data, but also synchronized data across all spans of biomedical devices and this is an area, as an example, where device intermediaries can excel.

Throughout my career, the most obvious problems in terms of interoperability and interconnectedness, which have impeded the seamless and complete integration of biomedical device data, have been essentially in the construction of or the need to construct device drivers for standalone biomedical devices to enable proprietary data access contained within these devices. Many of these devices do not use anything akin to network time stamps or network time protocols and hence, as a result of that, require or necessitate biomedical engineering, for example, to synchronize devices across multiple tiers, in terms of whether the physiological monitors and mechanical ventilators. Any nurse who has, for example, charted vital signs in acute care setting may have experienced the problem where data shows up in different columns or columnar format in nursing flow sheets and this is, to a large degree, dependent upon the time stamp differentials or problems that occur, synchronization problems that occur across biomedical devices.

This is not just a problem of device interoperability, but it is a problem in synchronization and, indeed, there are real clinical outcomes and real clinical responsibilities associated with being able to synchronize data. Standalone biomedical devices, which do not employ device gateways, that is, devices that typically are not physiological monitors or large infusion systems, do not communicate according to common methods. This makes the problem even worse. As a result, save for certain exceptions in the physiological monitoring space, this basically applies to mechanical ventilators, ad hoc or spot vital signs monitors, anesthesia machines, many of them standalone devices, such as glucometers, spirometers, pulse oximeters, blood pressure cuffs, etc. In other words, the vast majority of devices that are essentially being used in the home environment as well as in ad hoc spaces within the healthcare enterprise.

As a result of the proprietary and vendor defined mechanisms for device communication drivers are necessary to actually translate from these proprietary vendor-specific environments into a more standardized format, such as HL-7 solicited and unsolicited observation reporting and the extension to patient care device communication. But HL-7 is just the beginning and not the end of standardization that is actually required to ensure data integrity in terms of biomedical device communication. As a messaging standard, it is good, relatively mature, but in terms of the more sophisticated two-way communication, especially, that in terms of clinical decision support, clinical guidelines, for example, would require to support there's a long way to go. It is really inadequate at this stage to be able to support interactive communication.

It is an extremely embryonic area, and one in terms of the data integrity and management area that really needs some focus. If I could wave my magic wand and change one thing—or I believe what the term was used earlier today, my desideratum, as it were—would be to enable biomedical devices to communicate easily and ubiquitously. Just as you could plug in a USB cable into a computer have them recognize, have them associated with a common time stamp using a network time protocol, have the data securely accessed, reliable, scalable without having to worry about specific device drivers from specific vendors and at the same time have them associated with common time stamps. This, especially, is a problem when you're talking about home care devices versus devices in the hospital enterprise or in a physician's office wherein if you need to integrate this data in order to develop a more holistic picture of the patient you need to have data that are time aligned. That are according to common standards in terms of definitions, semantics as well as some tactic definitions, commonality as well as being able to overlay these data so that you can integrate and fuse a better position or better understanding of the patient.

Finally, in terms of data communication, I mentioned HL-7, but in addition to that the guideline interchange format and the Arden Syntax both methods for essentially using rules or developing rules for the basis of assisting in clinical decision support. Both require feeds from biomedical devices in order to be able to integrate the entire picture of the patient, from notes, from labs, from radiology as well as from the devices from the documentation systems to be able to pull together the entire picture for the patient.

With that, I'll conclude my prepared remarks. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Now we'll turn to Marlene Haddad on the phone.

Marlene Haddad – Department of Veterans Affairs – Clinical Data Quality Specialist
On behalf of the Department of Veterans Affairs, I would like to thank Mr. Ferguson and the committee for the opportunity to provide testimony this afternoon. My name is Marlene Haddad. I'm a Clinical Data Quality Specialist with the Office of Informatics and Analytics for the Department of Veterans Affairs. The VA is a strong supporter of the High Tech Act and the work with the Health Information Technology Standards Committee. We are focused on providing patient-centric healthcare that facilitates evidence-based decisions for individual veterans and their families, patient populations, clinicians and those managing healthcare delivery systems. The VA has experience with a broad range of medical devices in many healthcare settings and fully endorses the need to further device interoperability standards enabling the exchange of clinical information using the latest computer science methodologies.

I am so happy to have had this group before us speak. I know Charles specifically spoke to this, but in terms of data accuracy and integrity, it's really important to make that distinction between device connectivity and interoperability. So, connectivity is that ability of a device to stream data to charting or archiving system and a capability enabled by that connectivity in interoperability. That includes the ability of a device really, ultimately I think, to pass data or receive data from a third party device and pass control commands or receive control commands from that device if it's permitted.

So, I'm in St. Louis. I'm stuck in St. Louis today because I was recently on spring break with my three little people and severe weather in the Midwest called these weather delays and airport incidents and flight cancellations and had me thinking about the kinds of interoperability and plug and play control that happens with automobiles and aircraft and the fact that that's really lacking in our healthcare industry. And the high reliability and security of those information systems, advisory alarms, and safety interlocks of the commercial aircraft are good examples of what we really need in healthcare to really have, what I say, that gold standard for clinical decision support.

That sort of automated decision support is still generally absent unless, in the VA we have some workarounds that we are able to create that on our own, but it's really we would have to say "automated." So, the complexities of clinical device interoperability for data accuracy and integrity impel healthcare providers and systems to consider a broad range of device-specific issues and ensure that there is close coordination with all the people we've talked about today: clinicians, patients, biomed engineers, technical staff, Health Information Management, as well as standards development organizations and the industry in general. These considerations include the need to scale from fairly simple devices to complex systems, risk mitigation, hello? Did I get disconnected?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No, here you are.

Marlene Haddad – Department of Veterans Affairs – Clinical Data Quality Specialist
Okay, so anyway, I guess, I don't know where I left off, but I guess my thought is—as a middle-aged woman I can't continue a sentence past one interruption. But I will say a foundational aspect of this complexity is to make reliable a sort of combined human and system workflow that leads to the unambiguous, reliable identification of a patient and the unambiguous, reliable association of that patient's identity with all of the electronic communicating devices involved in monitoring and the therapy of that patient. I think we've touched on that today, but I think that if you don't have good, accurate and reliable data you just compound that problem further.

So, I think to give the vendors a little break today, I think that involves complicated work and data flows and the challenge is not just limited to the area of medical devices or that of our step-sibling, the middleware, but also careful planning of the human workflows as well, and that onus is on the provider system. So, our goal in the end is to implement the right solution for the right setting in a timely and accurate manner that benefits the patients and clinicians and improves the quality and safety of care

provided in our healthcare systems. I would just like to say that the VA appreciates the opportunity to express its views.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much, Marlene. Next, we'll turn to Karen Thomas.

Karen Thomas – Advanced TeleHealth Solutions and Oxford HealthCare – President
Thank you very much. I want to thank everyone for allowing me to take this time today and I wanted to mention just a little bit about why I'm here originally. We have had a telemonitoring program since 2002 and have monitored thousands of patients. My goal today is to respectfully request that the committee would include device standards for home health technology within their scope. Even though home health patients as far as a percentage of the total healthcare system, it would be considered small, the patients that people are taking care of at home are usually those patients who are very needy. They are high utilizers of system resources and they're usually most at risk for re-hospitalizations. So, even though it's more like the top 5% that's really going to require the most resources, even though it's a small percentage of the system in total.

The home health industry has become more sophisticated over the last ten years. Sixty-five percent of home health agencies employ an EMR now. Another 64.9% are using point of care devices in the field according to the National Association of Home Care. Another 23% of those agencies have already deployed and are using remote patient monitoring and, as with the EMR, that is a non-reimbursed expense, but they have seen the value in doing so.

I think, from what we've talked about today, I'm not going to go through what remote patient monitoring is. Obviously, everyone is fully aware of it, but I think it's really this adoption of technology that demonstrates that home health has become a sophisticated component of the healthcare delivery system. Not only have they developed their technique and employed more technology out in the field, home care couples this technical ability with an in-depth knowledge of managing patients in very diversified home environment, which can be challenging many times. If we think about it, the care for the patient in the home, even if it is just a Medicare episode, which runs approximately 60 days or the future management of the chronically ill patient, remote patient monitoring and other home-based technologies allows the home health agency to provide cost efficient care on a timely basis with daily oversight.

The real key is that this remote patient monitoring is an extension of the physician or the hospital oversight that would not otherwise be available and it is an additional databank of pertinent information regarding the patient's condition. I know there was previous discussion about whether or not they were FDA approved devices or patient purchased devices and I'm really talking about the FDA approved medical devices in regard to sharing of that data where there is some control over the type of equipment.

Obviously, we've talked about it many times earlier today, but it's important that these device standards, if they're included in this, they will ensure data accuracy and integrity because that data is being shared and it will help us support the meaningful goal use of reducing hospitalizations. This information is shared with a physician many times and a physician will make a clinical decision based on the data they're giving, so, obviously, it is important that this information is accurate and is timely.

This information has, in many cases, enabled to eliminate or reduce office visits, hospitalizations and emergent care visits. So, obviously, it's important. If we talk about the experience we've had in difficulties it would be individual mapping, which, obviously, you talked about at great length earlier. It's time consuming and it's also very expensive and if you use more than one type of monitoring device, you will have to deal with additional expenses for each device. Also, the data integrity and interoperability is very important to home care because it is key to that partnership that home care has already developed with physicians and hospitals and standardization of communication will improve that working relationship and, obviously, produce better outcomes for the patient.

We talked about it a lot earlier, so I won't belabor the point, but I think the information should be two-day, both information coming from the EMR to home health and then back again, based on the type of data

that is needed in the EMR. I want to point out there are a lot of things that are very important to a home health agency, when taking care of people in that environment. Even though it may seem to be a very small issue, it is really a large issue and it accounts for a large percentage of re-hospitalizations. That is complete knowledge of the prescription medications and other things, whether it be vitamins, herbal supplements, etc., what the patient is taking in the home and it's really amazing that between the hospital, the physician and what the patient is actually doing very seldom ever match up 100% when you're in the home. If I can wave a magic wand, obviously, it would be standardization for the continuation of care. But the other would be that reimbursements and incentives are aligned so that we reach our goals of standardization, cost of care and reduction of re-hospitalization.

The one thing that I would like to end on is that a key advantage of remote patient monitoring is you're truly assessing a patient in their day-to-day environment versus a hospital setting. Everyone knows hospital settings are somewhat controlled and these patients are handling their life in their own individual way and having that oversight in the home really helps the patient become more accountable. You do have to spend a lot of time educating the patient, but you get the patient's involvement and therefore you can improve care. I would ask you very respectfully that we keep in mind the speed of the technological advances out there and if we will pull in the home health monitoring and develop standards for these devices before there are so many devices that the technology gets away from us. Then it will be more difficult to pull it back in later.

Once again I would like to say that I think if we do this correctly we will find that the devices used in the home, they will increase and it will enable us to do a better job at the continuum of care and closing the loop. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Before we take questions from the workgroup here in the room, again, I want to turn to our members on the phone and see if any of your cards are up?

Joyce Sensmeier – HIMSS – VP of Informatics
I do have a question. My question is to Marlene Haddad and thank you so much for your remote presentation. I appreciate it the information. In my previous conversations with Linda Fischetti, who I believe you work with in her role as the chief health informatics architect, she's talked about the concern she has for her nurses. Currently—well, at the time, I was talking to her, which is probably two years ago now—she noted that they are capturing the pulse oximetry data manually and then re-entering it into the EMR. The impact of that on the things that you discussed and this panel is discussing, data integrity and accuracy, but also certainly there's the concern for efficiency of data and the work flow and the use of the nurse's time there doing that. I'm wondering if in these two years if that has improved at all and, if not, what are the things that you're considering in the future to address that?

Marlene Haddad – Department of Veterans Affairs – Clinical Data Quality Specialist
Well, I might refer that to Sarah to see whether or not it's improved or not, just that she's at a facility and that would be out of my scope of practice as to whether the process itself has improved. In general, I would say what we found is we really have got to do a lot of work to understand work flow process, in general, so that it's more than just, like I say, getting the information. But it's also understanding the work that's actually happening at the bedside, so getting more clinicians at the table so that the solution becomes more than just a technical solution. I would say what we've discovered that there are benefits—and I'm going to say it out to this group—and there are drawbacks at times to standardizing data. So standardization is definitely one tool and it's a great one to pull out of your toolbox, but there are times and instances where we've had to sort of think outside the box, but in terms of what's happened specific to pulse ox, I would refer that to see if Sarah can answer it.

Joyce Sensmeier – HIMSS – VP of Informatics
Sure, and I could have addressed that earlier. I'm not sure if Sarah is still available, Jamie, or not?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No, I think she's not available right now.

Joyce Sensmeier – HIMSS – VP of Informatics
Okay, all right. Thank you for addressing that, Marlene. But it's certainly not just VHA; I know of multiple other of my colleagues who expressed the concern about the duplicating of the data entry and the desire for it to be able to be automatically streaming from one system to another, but we've talked about the challenges throughout the day.

Marlene Haddad – Department of Veterans Affairs – Clinical Data Quality Specialist
Well, we do have, in our units we have like a sys arch program that will put that pulse oximetry information in to the clinical flow sheets, but I'd be guessing to know how that's happened on each individual ward and in certain specific circumstances.

Joyce Sensmeier – HIMSS – VP of Informatics
Okay, so certainly for this panel's consideration there are many barriers in this area. Thanks, Jamie.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Do any of the other panelists want to respond on the general issue, though, of how big a problem data re-entry is to accuracy and integrity?

John Zaleski – Nuvon – CTO and Vice President of Clinical Applications
As I mentioned in my remarks, or at least it was implied in there, what we're seeing with our newer customers, especially, who are installing inpatient systems is that the connection of devices in the inpatient environment is becoming expected and it's just part of the install that you do. It's not a question of whether a pulse ox is going to get entered by hand or other physiologic information is going to get entered by hand. Part of what you do during the install is you hook up the devices. That may be a factor of the customer base that we have, perhaps. The smaller community hassles and things like that because of the cost involved you may see more of the hand entry, but the experience that we're seeing now is just becoming more and more expected.

M
Depending upon which hospital enterprise you're talking about, there have been studies performed. We have conducted them as well in previous lives of mine and the savings typically can be measured in terms of several variables. One is timesaving, clearly. But the other is reduction in number of errors, but it truly depends upon the specific work flow. For instance, if you're talking about a med surg unit, in which our nurse tech is wheeling around the Dinamap or a vital signs monitor, then the mechanism for communicating the data could be on the monitor itself or could be associated with the monitor and ultimately it needs to conform to the nurses' or nurse techs' work flow. What are they normally used to doing? If they're traveling in a unit of 40 beds and it takes them 90 minutes from start to finish, clearly if they're not communicating this data all the time, that is, they're writing it down, one, the data are delayed in getting into the EMR. And, as an example, if an elevated temperature, an elevated blood pressure needs to be entered so that an order can be written on a patient then that is a delay. Concomitantly, that could affect the patient.

In the studies that I have personally run and, again, I'm not going to embellish this, it depends upon the specific unit, the specific hospital, so your mileage may vary, but savings in terms of 50% can be achieved in terms of the actual collection of data. In terms of reduction of errors, that's more of a testimonial because no one overtly wants to make an error, but they do happen. The obvious reduction in error associated with automatic association of the patient through a bar code, as an example, through a unit at the bedside, or something comparable to that, that can enable identification of the data. And then transmission directly into the record when it's accepted or validated from that point of view clearly can reduce the resurgent errors associated with re-entry of the data. So, the mileage can vary in terms of the savings, but in terms of the benefits the less human aspect of this, perhaps, is time, but it does translate into higher quality associated with individual patients.

Marlene Haddad – Department of Veterans Affairs – Clinical Data Quality Specialist

Well, I think to highlight Joyce's point; it becomes more than an issue of just having the pulse ox information in the medical record. So an integrated care environment, like a unit, that it's the conversion of that value into something that's in accordance with whatever your institution's preset specification is so that an alarm could be triggered to say, "Hi, Nurse Judy, that pulse ox is now down to 80, you might want to check your vents." So, that's the sort of interoperability I think that we're hoping for.

Joyce Sensmeier – HIMSS – VP of Informatics
Marlene, great point on that. I think the other point that Marlene made earlier that needs to be expressed a little bit more is the involvement of clinicians. Another barrier that we're seeing is that we don't have always enough clinicians representing what the work flow is, the challenges that they're seeing or even bringing forward their informatics expertise to the table, so I just wanted to raise that point again.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Great. Thank you very much. So, I want to take the question in a slightly different direction. I'm going to direct this at Tim Escher, but anybody else could answer this. I think, Tim, you very eloquently in your testimony identified a number of challenges in implementing interfaces, talked about how complex and costly and resource intensive that is from your customer's perspective. So what I wanted to ask is, back to some of the same line of questioning that Wes was asking earlier, what are some of the steps that you think could potentially be taken to make the implementation of interfaces cheap and easy for your customers, perhaps in stage three of meaningful use?

Tim Escher – Epic – Software Developer and System Architecture Engineer
Well, we need to, again, differentiate between the clinical setting and the home care setting. The home care setting is really fuzzy right now where we think that's going to go. In the inpatient environment cheap and easy—I don't know if every cheap and easy—but in our experience we implemented interfaces mainly through middleware and so we have one vendor that we work with quite a bit that provides a middleware device that connects to the hundreds of different possible endpoints that you may want to connect to. Then there are two other vendors who actually produce devices—very large vendors who produce devices and have their own middleware that we connect to as well. They provide an HL-7 feed, in all three cases provide an HL-7 feed out of there.

The challenges involved fall into two areas. One is just the logistics of testing, you know, testing all the possible different parameters, all the possible different devices that you may have in the different settings. Then the second portion of that is the mapping, which was just talked about in the case of the pulse ox and getting a value and understanding what that value means. I think what was talked about in the previous panel through the Rosetta Stone work that they're doing to try to come up with standard parameters and a standard vocabulary and semantics around all of that will help quite a bit in that. If we can go in and say that we know what these parameters are, we know what they mean because they meet a specific spec and a specific semantic profile, then it's a matter of testing the device and testing the connectivity and make sure the stuff gets stored in the right place. But we know what it means when it gets in there, so we think that will help a lot.

I also agree with Charles from the previous panel in that I don't think that the middleware aspect is going to go away. Not because there will always be a lack of standards, but I think there will always be the need to, especially as we get along in the device and we begin monitoring more and more stuff and you get more and more smaller end points. It will get more and more expensive to put more functionality into those end points when you want to keep those end points cheap, but allow them to be consolidated through sort of a device, but still standardizing between that device and EHR will help a lot. We think the PCD and RTM work will help with that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Now, let's see, I don't see any—oh, sorry, what? Go ahead.

M

So, Tim, I thought your discussion on stage two versus stage three was very forthright and I thank you for it. Do I recall correctly that part of what you were talking about with regards to home care is just simply the difficulty of getting devices running in the home?

Tim Escher – Epic – Software Developer and System Architecture Engineer
I think from my own personal use, I've personally used these devices, and considering that I'm in this industry I'm probably out on the tail in terms of the Bell Curve and people who understand technology and things like that and I struggle with it. We get some false readings. I had a cardiac monitor that I was wearing for a while and we actually got some false readings because the person I was talking to on the phone didn't understand which button was supposed to be pushed in order to get the recording sent back in. It wasn't automated and so on. I'm just thinking about my 85-year-old and 95-year-old grandmothers trying to do that and it's just not going to happen.

So a lot of that needs to be automated. It needs to be very straightforward and basically invisible to most of the patients as to what's actually being done and we're not to that point yet. My concern on either putting mandatory regulations or putting a whole lot of work into standards right now when it really hasn't shaken out in the industry what the usability factors of these things are may be counterproductive.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think that Karen wanted to jump in on that, Steve.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst
Oh, sure, okay.

Karen Thomas – Advanced TeleHealth Solutions and Oxford HealthCare – President
In regards to the use of devices in the home, there are a number of different devices out there. I have to say some are easier to use than others and I have had experience, not personally, but with some of the cardiac monitors and I have found sometimes it's the monitor, sometimes it is the person in the back office that's not providing what I would say good customer service. I will say, though, that we have hundreds of monitors out every day and we have people in their 90s and it's amazing how savvy they are. They are capable of being used. There is the responsibility of the home health agency that is using them to make sure that either the patient or a caregiver in the home is well educated.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst
Sure, one case I think we can distinguish is where there's an active home healthcare professional visiting the patient who can at least work the patient through that initial set up in trying on the device and so forth and making it communicate. Is that correct?

Karen Thomas – Advanced TeleHealth Solutions and Oxford HealthCare – President
Yes. What we have seen in different areas—because we also work with a younger population, a geriatric population over mid-70s to in the 80s, I would advise someone going out to the home and showing them how to use the device. Then we do a return demonstration while someone is in the home and make sure they're comfortable with it. We use more than one type of monitor. Another monitor, it's very simple, we can set it up in the office and ship it to someone. So, it depends on the device and the physical condition of the person that's using it.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So, what you're saying right now is that there are different characteristics of the physical product and of the organization that provides it that lead to differing results in terms of how easy it is to use, is that correct? And in the patient.

Karen Thomas – Advanced TeleHealth Solutions and Oxford HealthCare – President
Well, we have found there are very few patients that can't use the devices that, for instance, a remote patient monitoring that's gathering the vital signs. I'm not talking about the cardiac monitor, but we have not found it difficult to educate the patient and we calculated that we have probably 2% of the patients

choose not to use it, the ones we've placed the monitor on. We're replacing monitors on patients with four to five comorbidities that are at the highest risk for re-hospitalization.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay, so I think what I take particularly from Karen's clarification here is that if we're careful to sort out the use cases, if we're careful to look at more than just technological standards, if we're careful to talk about it being used in the context of a clinical protocol and so forth, we have the ability to move things forward. I think we also heard testimony from partners earlier today about chronic disease in presumably younger people where difficulty in getting the device to work had an adverse impact on a number of patients who stayed in the program, diabetes programming, diabetes measurements, for example.

I know that there is a move afoot. I'm not sure that it's good or bad, but it's characteristic of how industry attitudes are changing about healthcare. There's a move afoot for very large communications companies that have people who routinely go out to the home to install things—I'm talking about phone companies, cable companies, things like that—to be able to set up a home device for someone and make it work. So, I think we need to do some work to sort out what we can do, how to separate the cases into those where there really is no immediate impediment to going forward, as Karen is describing. Those that might broader impact or maybe, I don't know whether it's just following the chronologic care model or what, but where we would like to see ONC send a signal to industry that it's worth such an investment and what we can do about it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Sorry, Tim and then Karen and then John.

Tim Escher – Epic – Software Developer and System Architecture Engineer
Kind of to what's his point a little bit, I would not only look at the use cases, but I'd look at the economics of it as well because, as I mentioned, we have a total of a handful of customers, less than a handful actually right now, that are actively doing it. It's a little bit difficult to know why that number is so small. Is it because the devices aren't there? Is it because the data is not useful? Or, is that the ROI isn't there? The return on the investment of actually using those devices versus the money that could be used elsewhere, or is it a lack of reimbursement that might be as a part of that. So I think as you look at this you need to look at all those factors and make sure that the ONC doesn't say go make an investment at this, but making sure that the investment is the best place, not saying it is or isn't, but it's something that needs to be looked at.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
You would continue to express concern about any activity for stage two then, is that right?

Tim Escher – Epic – Software Developer and System Architecture Engineer
For stage two, yes. I think for stage three it's up in the air. Look at it in another year or so and evaluate and see where it's at, for the home care side.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Karen, I think you wanted to respond on that as well.

Karen Thomas – Advanced TeleHealth Solutions and Oxford HealthCare – President
Well, what I was going to say, there are a lot of things afoot now and different pilot programs or demonstration programs that people are looking at and you're seeing a lot more attention being paid to remote patient monitoring. I am an accountant by training, so the ROI was there for us. The other issue is I think that some agencies have just looked at it because it wasn't reimbursed and depending on their set up, it's a little harder to justify easily, but it's a worthwhile investment. We have done a number of projects that we have documented with outside companies to prove that we were able to reduce re-hospitalization and ER visits by over 50% for the chronically ill. Then we're currently doing a control group project now for re-hospitalization for heart failure patients, which thus far, halfway through, is very successful, which in turn will be a great ROI for hospital systems, too.

I would say—to go back to what Marlene said, the reality is that first, to back up, the reimbursement—if the reimbursement is there over time I think you'll see more people easily move into the arena. However, I think you're going to see more use of telehealth because of the ACOs and patient-centered medical homes. At the end of the day, it also takes a work flow analysis and really working with this data and understanding. Our nurses are chronic care certified, they have motivational coaching and we all know you do better if someone is watching over you. It's a very inexpensive way to get the outcomes that we're looking for.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
All right, thank you.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Jamie, I had a question. Wes' comment categorizing this really reminded me of it. Throughout the day I think almost subliminally I've been thinking about devices that, you know, you walk over to in your home, like a cardiac monitor, for example, where you carry it around or something. Are the testimonies that we are hearing today intended to include implanted devices, like a pacemaker that might be remotely interrogated or remotely reprogrammed or something like that, or is that yet another category of home device or remote device?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
John, do you want to take a crack at that?

John Zaleski – Nuvon – CTO and Vice President of Clinical Applications
Well, I think that ultimately, in the long run anything is on the table, but the question is, again, intended use. What is the objective? I think that I support my colleague's statements in saying that I think we need to look at both the economic as well as the patient wellbeing in terms of the benefit. I am certainly for, down the road, being able to support that, but there are a lot of questions related, what are the impacts potentially to patient safety, what is the objective, what is the intended use?

In these discussions, in general, I agree and support the statement that we should really be focused on approaching this from a use case perspective. Identify what specific problems we're solving and then the technology should be able to support those specific problems. Many times we tend to look at the technology and then assume that it will apply to all use cases, but there are many—whether it's another ambulatory environment or it's the end patient environment—many use cases, many different uses for the data. As Tim pointed out, in terms of the economics we may be finding a solution for which there is a very small problem, at least currently.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I think that most manufacturers of pacemakers are doing remote interrogation at the very least. I don't think that this is an outlier at all.

John Zaleski – Nuvon – CTO and Vice President of Clinical Applications
No, it's not intended to say that it's an outlier. The question is what specific purposes do we want to do this? Are we doing this for the purpose of evaluating the behavior and benefit and health and well-being of the device, or are we using this for clinical benefit and then to what end? So, as I said, I support the idea and the capability. What I was referring to is the fact that I think that in all cases we should be use case driven in terms of what the benefits are to the patient and to the care provider.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Do we have any other questions from our committee members on the phone? Okay. I see no more cards up for this panel. So, thank you all very much. I really appreciate you being here, providing us with your insights and a great discussion.

What we'll do now is we will take a short break and we will come back at 3:00, at the top of the hour, with our panel on, what's that? Well, that's a little over 15 minutes. Okay, so we'll come back, but everybody

please be back, ready to go, at least by 3:00, so long enough to get a cup of coffee, whatever, and this will be our panel on device security and data security and then we'll keep on schedule.

(Break)

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, if everyone could please take their seats. So, now we're on to the panel on data security and device security. We have Patrick Heim, Todd Cooper, Richard Eaton and Rik Primo. So, thank you all very much for being here today and providing your written remarks and we'll start off with Patrick first then.

Patrick Heim – Kaiser Permanente – Chief Information Security Officer
Thank you, Jamie. I'd like to thank the committee for inviting me here today. I've been sitting quietly in the back, listening and learning and quite honestly learning quite a lot. I'll be bringing a slightly different perspective to the discussion today than many of the other panelists. My primary function with Kaiser Permanente is as the Chief Information Security Officer, so talking about biomedical devices, that's really a small part of the overall environment that I'm in charge of protecting at this point in time.

I'll also be providing the perspective of somebody who has been in information security for a significant portion of my career in roles of auditing, testing, as a security product vendor and, more importantly, somebody who can represent more the dark side. Part of my career has been running teams who were in charge of actually breaking into systems and I think applying that perspective in thinking is, hopefully, going to be somewhat unique here.

I will skip the basic comments around Kaiser Permanente I've written here—I think Dr. Hyatt already introduced the organization—and dive right into to the testimony. So, as medical devices become more integrated into the enterprise network security capabilities and defenses of the devices need to keep pace. Definition on adoption of granular security standards for functional security capabilities, such as logging; data protection, such as encryption and integrity issues; authentication authorization of devices and users; identity directories; integration and mutual authentication. Device security maintenance, such as configuration management, patch management, mutual authentication, vulnerability management; and quality of the application implementation, such as designing robust software code will help address many common security concerns. In some areas, mature industry standards, such as secure wireless network protocols and central authentication, but should be more widely adopted and implemented in a manner that enables integration into existing infrastructures at customer sites.

In the area of information security standards or standards related capabilities that are most relevant and important to the meaningful use of EHR technology would include standards targeted at manufacturers of biomedical devices. Such standards would define functional security requirements, data protection, authentication and authorization, device security maintenance and quality of application implementation. The desired outcome of standards development would be certification that assures customers that the standards requirements are met. These standards should also require periodic reassessment of the effectiveness of the controls with the understanding that any computer system faces dynamic threats and vulnerabilities.

From a security perspective, a key barrier to effective use of healthcare devices to advance health and wellness is the lack of sufficient protection against privacy and security threats to prevent unauthorized modification and interruption to direct patient care, which could impact patient safety and quality of care. Moreover, widely publicized security or privacy incidents related to biomedical devices could negatively impact the confidence that patients have in relying on these devices and therefore inhibit the adoption of telemedicine. One change that would enable more effective and widespread use of healthcare devices would be for the healthcare industry to differentiate itself from other industries by ensure that security controls for devices are integrated as upfront capabilities rather than waiting for dramatic failures to motivate implementation of these features.

On the area of device security and data security, in a care setting there are different requirements, depending on the care setting. Different care settings, such as skilled nursing facilities, hospital, home or

other remote sites present heterogeneous user, clinical, technical, environmental and regulatory characteristics that contribute to different security risks with medical devices. Devices used at provider managed care settings, such as in a hospital or skilled nursing facility are usually shared among multiple clinical users in caring for different patients. Devices used in these provider-managed settings are typically operated by trained professionals. They are used to provide more critical or acute care and may be increasingly so connected to an enterprise network of clinical grade rather than consumer grade and subject to greater regulation. In a provider managed care setting, there is a greater likelihood that robust confidentiality controls will be implemented because of regulatory requirements, organizational policy and more widespread access to the devices. When a medical device is employed in an acute or critical care setting, it typically requires higher availability protection.

Clinical grade devices may contain critical decision support functions, such as dosage checks in smart infusion pumps. Thus, illegal tampering will present higher threats to patient safety. Therefore, devices in these settings require high level security protection for data integrity. Additionally, as medical devices become components of the enterprise network infrastructure controls, such as intrusion prevention, become mandatory with provider managed devices. Different provider managed care settings also require different risk management approaches. For example, frequent inactivity time out is commonly enforced at ambulatory, skilled nursing facility and other episodic care settings, but much less frequently within a highly critical and tightly controlled environment, such as an operating room or ICU, where regular provider monitoring is routine.

In the home environment, there are different threats and vulnerabilities. User authentication may be optional or minimal. However, because users of those devices are not trained professionals or necessarily technology savvy, controls aimed at reducing user errors become important. Some examples include easy and effective ways to identify the patient, and removal of higher critical clinical functions to limit the attach surface. Additionally, consumer privacy preferences vary widely and consumer devices should provide affordable, privacy protection security options, such as encryption.

We see two major opportunities for improvement; security standard development specific to medical devices and certification processes that validate that the standards are appropriately implemented. Medical device technology security standards exist today mostly to meet medical device interoperability related needs, such as network transport security. While some address hit the related confidentially issues, few appear to be constructed to tackle a broader set of security requirements. Other industry efforts also exist to define best practices with medical device security controls, but most are overly general and vague and not conducive to tangible improvement of security controls with network enabled devices. End-to-end use cases that test the validity and sufficiency of the security controls have not been developed and analyzed.

An industry effort similar to the Biomedical Device Innovation Safety Security Consortium, co-led by the VA and Kaiser Permanente would be necessary to identify and prioritize security use cases that reflect a variety of threat models with network biomedical devices. Overlay the use cases with existing security standards and identify and bridge any critical gaps that might impact confidentiality, integrity and availability. Those technical standards must be sufficiently specific for vendor testing and adoption. Security assessment, including control validation and penetration testing with network medical devices require highly skilled professionals. The outcome of such assessment could benefit a large population of care providers, patients and manufacturers. Currently, such assessments are conducted, if at all, by individual providers, involve high cost and low consistency and present very limited incentives for device vendors to improve their security design.

Improvements in the testing and certification area will help drive better security standard definition as well as adoption. Security needs to become a competitive advantage for device manufacturers. The primary issue with intermittent connectivity relates to—and this is talking about network and connectivity issues in response to the panel's question—the primary issue with intermittent connectivity relates to the integrity of data, which is represented by risks of incomplete data and corrupted data. An option store and forward protocol is recommended. The design of remote monitoring systems should also consistently time stamp all data entries, time synchronize with authoritative time sources and provide a message digest, such as a

cryptographic hash or digital signature to detect any corruption modification before and after the network interruption.

Thank you for the opportunity.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Next, we'll hear from Todd Cooper.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
I have a few slides, which I'll be reading off of. My name is Todd Cooper. I am glad to say that it is now afternoon, so good afternoon in my hometown, San Diego, America's Finest City. I have five very brief points and at this point in the agenda is excellent because I think most of the topics, whether they vet my position or not have already been tabled and discussed at length. So I will be able to actually, hopefully, in the next few minutes focus on something that has not really been a strong topic of discussion, but as many of you, I also wear hats for different organizations, especially over the different years.

I'm glad to say, though, that some of you present have many more years in this area than I do. I've been very active in the medical device, informatics and interoperability space for about a decade now. I know many of you from different activities in that area. I'm going to focus today, though, on one specific area, which is my role as co-chair of Joint Working Group 7, which is focused on the risk management of IT networks that integrate one or more medical devices. So, I'll get to that in just a minute, but that will be the primary focus of what I'm going to say.

The number one blocker for EHR integration of medical devices is—I will put a fine point on—is the lack of sustained market demand. We've heard that a few times from different venues today. We've heard it from the manufacturers a little bit. In essence I thought, totally wrongly, that whenever we got an initial set of informatics interoperability standards in place that then the manufacturers would adopt those, implement those and the demand that we have heard variously from the market to implement those would be met.

I was shocked, at least for a few days, whenever we published those standards and then I saw the manufacturers take a step back because they said, "Well, actually we're not receiving any RFPs." Or, "We receive it from one place or another place, but we don't have the market demand that will justify the capital expenditures required to deploy these technologies, compared to the other opportunities that are in front of us." We have the same thing from the provider side, who say, "We keep putting this in. By the time we get through the RFP process, it drops off the end of the priority list for a number of different reasons and we could go into that." But I will still say that one of the key reasons or the key objectives or benefits that the ONC can play in this space is to help break that chicken and egg model that has prevented the widespread deployment of standards-based interfaces in this market.

An enabler for EHR integration, the number one element here is standards and is having commercially available products. I think what has changed over the last year especially, is now we are starting to see, especially with what you've heard with respect to IHE enabled products based on HL-7 and IEEE standards and terminology now being deployed more and more into the market. So if you were actually to plot this, you would see that it's gone up. We have a large number of major medical device manufacturers who are starting to deploy those, so that is a key change over this last year and that we're going to see in the next few months and through the next year, products based on these interoperability criteria. We've also seen a fair amount of usage of, as I said, these mature standard. So in terms of being able to call out medical device interoperability as a key criteria, I see that we actually are starting now to see the products available that would be able to enable that and that is, Wes, a change from what we've seen the in recent years.

The number one enabler of this is semantic interoperability and I think you've heard this a few times, especially with the Rosetta activity, so we've had medical device terminologies available. We've seen a mapping with this from vendor proprietary terminologies to a standardized representation and then usage of that widely in these interfaces to EHRs, so that has been a very big game changer, along with the

tooling necessary to be able to validate that those terminologies and semantics are being properly represented, so we see that.

I guess the last part of that is being able to find use appropriate mapping to also SNOMED CT and LOINC. But one of the issues that wasn't mentioned earlier today was the fact that with the device-specific terminologies—many times you end up with a 20 to 1 or 40 to 1 mapping to a more clinical level term, that's, for example, in SNOMED CT. However, whenever you get to a CDA or some other application you need that SNOMED CT mapping and you would like it to be normative, consistent across all applications no matter where they are. So we have active projects right now looking at mapping from the 11073 terminologies used by continuing a home care context, by IHE in the clinical context to SNOMED CT as well as to LOINC. So we see a great convergence in the uses of those terminologies.

Here's the main thing I wanted to focus on today and I see I'm out of time already, and that is the use of risk management. I will say this very quickly here—and you can almost read this diagram—what we've recognized is every medical device manufacturer has to go through very strong rigorous risk analysis to be able to prove that their system is safe and effective and can be marketed. What happens then? This is what the 801001 standard that was jointly developed between ISO and IEC focuses in on is how do you continue that risk management into a deployed environment to ensure that even if you achieve meaningful use in the deployment of your health information technology, that doesn't end up becoming a front page headline about a major patient safety incident that happens or major breach of security. Thank you very much.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Next, we'll move on to Richard.

Richard Eaton – Medical Imaging & Technology Alliance – Industry Manager
Good afternoon. My name is Richard Eaton. I'm the Industry Manager at the Medical Imaging & Technology Alliance (MITA) with responsibility for the medical imaging informatics section. MITA is the medical division of the National Electrical Manufacturers Association, which is the largest trade association representing America's electrical industry. With me today is Rik Primo. Rik is current the chairman of MITA's medical imaging informatics section. He is the Director of Strategic Relationships for the Image & Knowledge Management Division at Siemens Medical Solutions, USA. We want to thank the Clinical Operations Workgroup for convening this hearing and for this opportunity for MITA to share our views with you and to testify today. I'd first like to go into MITA manufacturers experience with healthcare devices and device interoperability.

MITA manufacturers have extensive experience with the manufacture, testing and deployment of medical imaging and radiation therapy devices, including x-ray, magnetic resonance, radiation therapy, ultrasound, molecular imaging equipment and radiopharmaceuticals. Our members also manufacture PACS (Picture Archiving and Communication Systems), RIS (Radiology Information Systems), and HIS (Hospital Information Systems). MITA members have been actively engaged in the development and ongoing management of several standards and standards related activities, which are key to establishing systems interoperability.

The digital imaging and communications in medicine, or DICOM standard, enables the communication of images and imaging information between providers. The DICOM standard is the standard for communication of imaging information and was created by MITA manufacturers and the American College of Radiology back in 1993. It is continually being updated and expanded to reflect new technologies and to serve evolving clinical needs. The DICOM standard has been adopted nearly universally and is available now for implementation. The HL-7 standard is used for the exchange, management and integration of data. It allows for the flexible and cost effective exchange of clinical administrative data to achieve interoperability between healthcare information systems.

Thirdly, the IHE or integration of the healthcare enterprise profiles, these are tools which employ coordinated implementation of established communication standards, such as DICOM and HL-7, to address clinical work flow issues to improve the way computers and healthcare systems share

information. MITA wants to recommend the adoption of the DICOM standard for the communication of imaging information and its incorporation as a key goal of stage two meaningful use. We also believe that a roadmap for use of images within certified EHRs that considers both stage two and stage three is critical.

Now, I'd like to touch upon key barriers to the effective use of healthcare devices to advance health and wellness. There are a number of key barriers. I will name several. One is the lack of access by providers and hospitals to the patient's medical imaging information. This is a significant barrier to the effective use of healthcare devices. This lack of access to this information hampers the ability to render a complete diagnosis of the patient's condition. Second, the substantial investment costs and training, which are needed to convert to an electronic health record system from a paper based system. This is also a significant barrier. Third, the widespread sharing of patient data between different healthcare systems has not yet become a reality. For example, when patients move to different health institutions to seek care this sharing is important in order to achieve a fully effective use of electronic health records.

Turning to security requirements, with respect to security requirements for devices MITA has been a co-sponsor of the Joint Committee on Security and Privacy along with European and Japanese Medical Imaging Device Trade Associations, both in Europe and Japan. Specifically, for example, SPC or the Security and Privacy Committee's published papers include, for example, "Information Security Risk Management for Healthcare Systems," "Security and Privacy Auditing in Healthcare Information Technology" and "Defending Medical Information Systems Against Malicious Software."

We found in various care settings the individual care setting rather than just the type of the care setting should determine the security measures, which are applied. Following is a recommended approach; first, understand the nature of the security risk; second, utilize a layered security approach; third, adjust device external controls to the specific installation and, fourth, provide specific controls directly on the medical device. In terms of security, MITA is also working with the Health Information and Management System Society (HIMSS) and other stakeholders to revise the currently existing manufactured disclosure statement for medical device security or MDS2. This will help potential purchases assess the security capabilities of equipment, which they are considering for acquisition.

Finally, how do existing security standards support network enabled devices today? With respect to existing security standard support of network enabled devices, the standards and mechanisms defined both in DICOM and IHE are robust and in widespread use to provide effective protections today. They are provided primarily through the use of the IHE Audit Trail and Node Authentication or ATNA profile, by authentication of systems and encryption of transported information, interoperable audit logs and user authentication and access controls.

In conclusion, MITA, again, wishes to thank the Clinical Operations Workgroup for affording us the opportunity to testify today. MITA is ready to lend its knowledge and expertise to the Office of National Coordinator and this workgroup to assist in facilitating the implementation of systems interoperability and to the implementation and testing of device security and data security. We look forward to working with you in this important effort. Thank you very much and we're glad to entertain your questions.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Next, we'll hear from Rik.

Henri "Rik" Primo – Medical Imaging & Technology Alliance – Chair, Medical Imaging Informatics
Actually, I'm here for technical support reasons, so I will provide answers on technical questions. That will be my pleasure.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Now, I'll check first, again, for our committee members on the phone and see if Joyce or Dixie or Don have any questions for this panel.

Joyce Sensmeier – HIMSS – VP of Informatics

Nothing from Joyce.

Don Bechtel – Siemens Medical – IT Architect, Standards & Regulatory Mgr.
Nothing from me yet.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, we'll go to Dixie and then Chris.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, last—well, I guess it was the fall of 2009 that Privacy and Security Workgroup held a hearing on privacy and security barriers and issues. The one issue that was brought up most frequently by our testifiers with respect to medical devices, had to do with the use of personal computers as part of medical devices, especially regulated medical devices, and the challenges that were faced in keeping those devices current with critical software updates and new virus signatures, etc. I'm kind of surprised that none of you mentioned that, so I'm going to ask you whether you see the integration of personal computers as part of regulated medical devices as an issue.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Looks like Patrick and Todd may respond to you.

Patrick Heim – Kaiser Permanente – Chief Information Security Officer
I'll respond first. You're absolutely right. I think in my testimony I mentioned around the ongoing maintenance elements of it and the threats that are evolving. Definitely a lot of medical devices are based on commodity operating systems, whether it's a Windows-based or embedded Linux of some kind. From an attacker's perspective or from the perspective of a worm going through your network, it doesn't differentiate between a medical device that may be attached to that or maybe that machine versus anything else that's out there. If it finds the hole, it will get in. So, it requires ongoing maintenance, patching being applied, version upgrades and whatnot.

Definitely with the constraints we have in terms of not being able to manage these devices ourselves there is a significant gap where there is an opportunity, say, for example, a network worm to infect via medical devices that have not been appropriately patched due to FDA constraints and that should be managed by the vendors on our behalf, basically. So, this is—and we see the data coming in as we have infections in some cases, that this is an area that does stand out as an area of concern, so the challenge I posed is how do we implement and how do we really have ongoing timely maintenance if the regulations prohibit us from doing this ourselves. If it doesn't appear; the evidence to me suggests that the vendors are not doing this as effectively as they could.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
Thank you, Dixie. Great question. One of the points here to start out with, you said, a medical device. By that designation, if it's a regulated medical device that means it's gone through the approval process, which means the manufacturer of that device has done extensive risk management, risk analysis, including identifying vulnerabilities or issues with respect to the maintenance of that device when it's deployed. One of the key problems that we have found, though, again, in the development of 801001 Standard with respect to security is communicating into that end user what are those potential residual risks that need to be managed and how might you manage those in that end deployed environment? So the breakdown of that communication and the breakdown of that communication amongst the many different vendors that are putting technology into that environment is one of the key issues that needs to be better addressed.

You also have a tension, a governance tension, if you will, between clinical engineering, biomedical engineering, who is often in charge of the medical devices themselves and those who are managing the IT network, especially security. So depending on how well those departments work together, how well their processes have been integrated, those risk controls may or may not be identified, that identification of potential vulnerabilities. And how, for example, do you manage patches in terms of keeping the safety

envelope intact on the device versus getting the patch out there to prevent virus infections across your enterprise?

That tension needs to be actively managed and monitored and that was one of the issues that we addressed in the 801001 Standard. Both in terms of what is the language that you use to communicate those needs and have that dialogue as well as trying to establish upfront how are we going to address this both within the deployed organization as well as between stakeholders, technology suppliers, so that whenever it actually happens you have a clear idea of who is going to respond to what and how to resolve the problem quickly?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, if I can just jump in to summarize what I think I just heard is that the theory is that these threats ought to be managed and the reality is that they're frequently not?

Patrick Heim – Kaiser Permanente – Chief Information Security Officer
Absolutely. Let me add a few more words to this also, so the practical reality is that if you are doing vulnerability management within an enterprise network you conduct security scams. The unfortunate reality is that we've had to take out of our security scanning entire segments of our network because they contain biomedical devices. The reason we have to take them out is because they are so poorly implemented that if we scan them, they will fail and crash. There is a serious concern about the robustness and the resilience of these devices.

Richard Eaton – Medical Imaging & Technology Alliance – Industry Manager
Case in point, I think there is very well-known incident that happened in the U.K. where the system went out and was scanning network attached devices that needed to be upgraded and it found one and it did it. The device happened to be in OR in active use—

(Audio drops out)

Joyce Sensmeier – HIMSS – VP of Informatics
So, I just wanted to follow this, though, because it seemed to me that Patrick was saying that under certain circumstances the places that have the devices can't update them because that puts them outside of the FDA thing. I think I heard Todd say that we have to really work it out because we have a communication problem because there are certain things that have to be done by the customers. So, this was beginning to sound to me, in a way, like HIPAA security and privacy regulations where no one was giving out the data because the federal government wouldn't let them. I mean, is there also a hand off problem or people can do things, but they don't know they can do them?

Richard Eaton – Medical Imaging & Technology Alliance – Industry Manager
Yes. I think your observation of the different perspective is absolutely correct. One of the issues that we've heard is that it's correct to the point that we don't necessarily need new standards, new guidance. We need to have better dialogue between those who supply these technologies, who have thought through all this process and those who are trying to integrate those and manage those in the end environment and that's not a one-time thing, it's an ongoing process that has to happen.

Patrick Heim – Kaiser Permanente – Chief Information Security Officer
It is an ongoing process, but as I look at the area of biomedical devices and, again, having probed my teams I'm under the belief that we are not allowed to update or alter them in any way except for periodic virus updates or what not. That binds my hands and I'm reliant on the vendors to perform the maintenance at this point in time. I'm also quite uncomfortable at having vendors coming into my network to do this maintenance at times. So, there are a broader set of security issues here that have yet to be resolved and I believe it goes beyond communication.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Next, we'll go to Wes and then Nancy.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So, I have a colleague who has been fairly active in health IT security and other kinds of security issues and he swears up and down that manufacturers that say you cannot post OS updates or virus updates are blowing smoke. The FDA has no such requirements. HIMSS takes the same position as far as I know. Is there any reason to doubt that?

Patrick Heim – Kaiser Permanente – Chief Information Security Officer
I'm not a regulatory expert and I haven't parsed the law, but you might say the mythology that's on the ground in the organizations where these devices are implemented is that they have very limited authority to alter the devices.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
What I hear is the vendors completely say, create the mythology. That is, they make those statements without having the regulatory back up. I started to first put my card up because I'd heard about sort of a limited set of security vulnerabilities primarily addressed through transport encryption and authentication and audit capabilities, but then in the other answers to the questions we got into some other interesting stuff. If I could summarize what I've heard, the instrument manufacturers as a group are producing and getting approved devices with networking software that wouldn't pass muster in any other organization. That is, it appears they were designed, built and tested on isolated network segments and they've never work in any other environment or at least they have all of the disadvantages that you've described of not being able to stand up to being scanned and things like that.

What are the policy levers that we have to change that? I realize we don't have regulatory experts here, but what are some ideas of what can be done at a governmental level? Maybe it's been done in other countries or something like that, that would create a set of instruments that were better network citizens. Rik, it looks like you had, yes.

Henri "Rik" Primo – Medical Imaging & Technology Alliance – Chair, Medical Imaging Informatics
Thank you, Wes. In imaging as long as you are within the walls of the enterprise, so to speak, you have fairly tight controls over the security of the data. The problem is if you want to share these images and, of course, we all know the light bulb jokes and how many healthcare providers does it take to exchange images? Only two, but they have to want to do it. So, at the moment that you want to make an exchange of images, you have a security risk. The risk is that an industry grade PC, consumer grade PC, could be used to look at these images and right there you have a security risk. So, what in the imaging industry is fairly common is that the manufacturers are publishing a list of tested virus scanners and that within the service contract that we have for the software of that imaging is that we publish regularly and test the new extensions of the virus scanners. Just assume that it will work has proven in the past not to work.

So, what we do is that as soon as there is a new McAfee out there with a new version, that we test it out and communicate that within, and that's the problem, within, say, four weeks to eight weeks. Now, within those four weeks you do, indeed, have a risk that a virus of the latest version could go in there. However, you need some time to test and we tried to limit that time to the absolute minimum. Further, to make sure that data are not accessible by people that would not be authorized to do that we heavily rely on systems like Active Directory, where we can consult a matrix of users and privileges to make sure that only the right people have access to data. Further, the data that resides on the PC will be automatically erased at the moment due to something that is called zero footprint technology. So at the moment that the user is logging out there is no image of the images on the hard drive or in the cache.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I'll just check if there are any other panelists responses to that, then go back to Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Because I'm really more interested in sort of the instruments in the hospital and things like that.

Patrick Heim – Kaiser Permanente – Chief Information Security Officer

So, let me separate out the engineering of the systems and the design from the ongoing management of the systems. Now, I'm going to flash back real quick to being in engineering school and I got to watch the video of the Tacoma Narrows Bridge being shaken because of resonance issues, if I remember it right, and it being a classic case of bad engineering. But the world of engineering in the physical world is very well defined and you know what you're building to and there are standards and there are checks and there are inspectors along the way and there are quality controls in the whole entire supply chain. Even though now, if you look at biomedical devices, people's lives are at stack being controlled by these devices. I don't see similar standards that really force quality of design and quality of engineering being applied.

What I was calling for in my testimony was thought around the creation of a certification process of sorts, so that I as the buyer don't have to have scanning and attack and penetration and you know what to test the quality of the products that I'm buying. I should be able to buy a product that is certified, that has been tested, that the best minds in the industry have banged their heads against trying to break into it and say it's robust and it's resilient and it's not going to come crashing down. I shouldn't be afraid that if I put it on my network, that if I scan it, it will crash. So, it's that, which is what I'm looking for, having a heightened level of assurance that what we buy is secure out of the box, not just from a feature set perspective, but it's a resilient product.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Wes, did you have a follow-up?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
No, I think Patrick helped quite a bit, thanks.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
It looks like maybe Jay or Terrie—do you want to comment on this particular issue?

Jay Crowley – FDA – Senior Advisor
I'll let Terrie jump into it.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Well, it's not really our role here today to be talking about regulatory issues, but we do want to refer to a guidance on diverse security that is on the FDA Website that does clearly state that most patches are not safety and effectiveness issues and it's the responsibility of the manufacturer to validate the patch. But it doesn't require any of the 510(k). So, we refer to that Website because we're not the experts on that, but it is on the FDA Website.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Just to follow up on that, from the panelists who have experience with the actual implementation of these issues, what's the timeliness requirement for getting these patches through the process to deployment? In other words, how fast, so if the current experience is it takes, say, four to eight weeks to through a testing process, how does that square with the life cycle of the threats?

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
My response to that I would say that, again, that is information that needs to be agreed upon and understood at the beginning of the acquisition process and so oftentimes you have in service level agreements between companies and end users, that is the kind of information that you include in there. This is what we can provide and, as I said, it's a dialogue, well, this is what we expect and need and then you figure out how are we going to come to a compromise ground on that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, I'll turn to Nancy Orvis.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

Thank you for that illuminating discussion we just had from Wes' question. I wanted to follow on a bit on what ideas could we think about that would work. Is there such a thing as a middleman kind of company that would sell a variety of devices to a provider institution who could do all of that, keep a list of all the software patches or security patches that would be done and do that with other manufacturers? Or are we looking at, you said, the way we're kind of sounding now is that there are 500 to 800 devices as a minimum in institutions. We know that. And I said, is that every single service level agreement between you and this and you and this or is there a viable way to get that done better?

Other than the fact that the one gentleman, Mr. Primo, said that they imaging industry already had, they would published a list of patches that they had tested. But even so, if you're saying there are 50 or 100 device manufacturers with the 500 devices, you're telling me that that currently doesn't exist in other parts of the industry on critical care equipment or they don't list normally what they've already tested? So, I'm just saying I'd like some feedback on whether is there a place for some distributor or something to work with these manufacturers to help them do that?

Patrick Heim – Kaiser Permanente – Chief Information Security Officer
I'm not on the acquisition side, and it was interesting for me to hear the perspective that this would be written into contract, that we would have a contracted SLA that defines the frequency of releasing patches and whatever the weeks may be. I'm not sure that the folks who engage from a contracting perspective with vendors would have the appropriate knowledge from a risk perspective of what the appropriate time period is. So, I'm in alignment with you that this is something that if I'm thinking about managing this at scale with a number of vendors should not be based on an individual one-on-one contractual relationship. At a very minimum based on some categories of risk, I'm not quite sure how to classify it, definitely there will be different time frames or time expectations.

For example, for systems that are Internet-facing for me, if there's a critical vulnerability, my expectation is 24 to 48 hours to have the patch tested and applied. If it's internal to my network and a less critical system, it may be let's wait three, four, five, six months until the normal outage cycle takes place. So, there are data elements that inform around the threat environment and the risk that's involved, how rapidly or how frequently you have to patch, but having that managed by some standard versus having it placed into a contract setting, a standards-based expectation I believe would be beneficial.

Richard Eaton – Medical Imaging & Technology Alliance – Industry Manager
I would say that there's a lot of activity right now to define—for example, templates—and I think the MDS2 is an example of that kind of a template. So in terms of both the language that was used to exchange this kind of information as well as what would be an example of an agreement that would have those elements to it. To be sure, if you've done a risk assessment, a risk management of these network technologies, then you have a baseline in which you can then go back. And whenever you have a potential incident or an event, you can evaluate that based on the level of risk criticality that can result and then have an appropriate level of response to that, be it 24 hours it has to be fixed, be it in the next week or two weeks. I know that's exactly what, for example, the NHS, they've done a safety management program that does exactly that kind of factoring into it. Was I totally opaque?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
The last acronym, who has already done that?

Richard Eaton – Medical Imaging & Technology Alliance – Industry Manager
NHS in the U.K.—the National Health Service in the U.K.— Dr. Maureen Baker, has a very well-developed safety program from the clinician on back to the back shop where they do that kind of assessment, where their event management, their call handling service, since they have that risk assessment, that risk management in place. They're able to quickly do a determination as to what kind of response needs to happen with that manufacturer and they have the contractual and procurement language in place to be able to guarantee that that actually happens.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

Just to clarify, that's regarding a lot of these clinical engineering type of devices, the bioengineering devices?

Richard Eaton – Medical Imaging & Technology Alliance – Industry Manager
Yes, absolutely. Network-to-medical technology.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Let me turn back to our members on the phone and see if there are any questions there.

M
Nothing on my side, Jamie.

Joyce Sensmeier – HIMSS – VP of Informatics
Nothing here. Joyce.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
No further questions here.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Somewhat unbelievably, I see no further—

M
I've got a question. Todd, since we have a moment here, the name of your company is –

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
80001 Experts. Yes.

M
How do you get all of those people in a room?

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
Yes. It's a trick.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Is there any further discussion with regard to this panel on these issues? Okay. Well, then I want to thank the panel very much for—

M
Actually, we do have another question.

M
What is 80001?

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
Yes. That was in one of those slides .... It's actually in my written testimony. It's a joint standard between IEC SE52-A, which is a group that's responsible especially for safety standards around the use of medical technologies, and ISO TC215 for health informatics. It focuses on how do you apply risk management, which is well understood in the medical device development standpoint. How do you leverage that whenever you're now connecting that same medical device to an IT network? So you have a general, open, heterogeneous network. You attach a medical device. How do you ensure that you're maintaining the safety, the system effectiveness and the security that has been designed in when it actually is then deployed?

M
When was this standard published?

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
It was published November of last year. I'm not sure if that was on your monthly cycle.

M
We need an acronym update too.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, once again, I want to thank the panel for a very interesting discussion on a set of very, very important issues. We are running a few minutes ahead, so we will take just a couple of minutes to set up for the next panel. So without a break we will set up and go forward.

We're ready to begin if folks could please take their seats. We're ready to begin our final panel, Unique Device Identification. We have a very distinguished panel here. From the FDA we have Jay Crowley and Terrie Reed. We have also Betsy Humphreys, Janet Trunzo and Jim Keller on this panel. Jay, you're up first with your slides.

Jay Crowley – FDA – Senior Advisor
Well, good afternoon. Thank you, all, for having us. We're going to shift gears tremendously on you all, so just get ready for a little bit of whiplash here. We've talked very interestingly about lots of issues associated with device interoperability, what that means from an EHR perspective and we're really going to take a very, very different view and we're going to talk about device identification, specifically I'm going to talk about unique device identification and its relationship to electronic health records and to devices in general. So it's very, very different than what we've talked about, so I hope you'll forgive us for really going down a very different path.

But what we're interested in and what I'm going to go into a little bit of detail on is actually documenting device use in electronic health records, personal health records and other clinical information systems, so using an identification system. We've talked about the implants a little bit. We've talked about a host of devices. Some of those are network devices. Some of those are standalone devices. We've talked about a whole bunch of different types of medical devices, but what we're interested in is actually seeing that individual device, that very specific identifier for that device, documented in various kinds of clinical information systems. There is a whole host of benefits that we think can accrue from that and I'll go into that in a little bit more detail.

Importantly, I do want to mention that I'm going to talk about two systems, if you will. I'm going to talk about unique device identification and I'm going to talk about the global medical device nomenclature, GMDN and others will also go into that and other nomenclatures. The idea here is that it's very important for us to be able to know the continuum of identification from a very specific instance of a device. It's this particular manufacturer's orthopedic implant, to talking about orthopedic implants at a high level. So what we're looking to do is really create this continuum of identification from a very specific granular instance up into, if you will, a high-level classification or nomenclature term.

The reason that we want to document device use in electronic health records, maybe it's obvious to you, but what we're looking to do is to be able to aggregate that data. You've heard people talk about registries before and other kinds of cost and clinical effectiveness concepts. What we're really looking to do is to facilitate that. So by documenting device use in these electronic health records and other clinical information systems we can then begin to aggregate that data in a standardized way and begin to do some of the things that are important to FDA and some of the other speakers talked about other benefits from that.

I just want to briefly touch on this; and maybe everyone knows this; but the term device, regulated device, medical device has been thrown around a lot today. It gave me quite a bit of heartburn to be honest with you, because to us this is something very, very, very specific. So when we talk about medical devices and from an FDA perspective it's a very, very broad range of things. Some people said devices were approved. Some people said devices were cleared. Both of those are true, but in different ways. There

are some devices, which are approved. There are some devices that are cleared. There are some devices that do not go through any sort of pre-market approval process.

So I just wanted to put this slide up to show you that we really mean, when we talk about medical devices and talk about documenting device use in electronic health records and other clinical information systems, we mean a very wide array of products. We've talked about some of the sort of integratable devices; ventilators, various kinds of monitors, infusion pumps were talked about. Glucose meters were talked about. We didn't really talk about some of the disposables and accessories that go with those products. A glucometer is only as useful as the glucose test strip that goes with it. Those are two different devices that are approved in two different ways and have, obviously, different identifiers associated with them. We talked about implants. There are obviously many types of implants. We talked a little bit about cardiovascular. There are orthopedic, lots of different types of implants. In vitro diagnostics (IVDs) are devices as well, both those that are used in clinical labs, as well as point-of-care kinds of devices. We've touched on HIT, which, of course, is also a medical device and I'm not going to say anything more about that. Then there are also devices—we've talked about home care a bit, but there are lots of alternative sites, a lot of devices used in the home. There are dental. There are lots of different kinds of devices. So, to us, medical devices means something very specific and there are lots of different kinds of them, but we're interested in the safety and effectiveness of all of those.

Why are we involved in this project, unique device identification? There is a whole host of benefits. Obviously, I touched on the concept of documenting device use in EHRs and PHRs. Why do we want to do that? To us that facilitates all sorts of post-market surveillance kinds of activities. Being able to identify a device very specifically also helps with our adverse event reporting. A couple of the speakers have talked about supply chain security and traceability and some of these concepts. Right now devices, you can't do many of these things from a device perspective because they're not identified at a granular level in a standardized and unambiguous way. We heard some speakers talk about registries, comparative effectiveness, clinical effectiveness. All of these are, we think, benefits that can accrue. Some of these, obviously, are FDA focused. Many of these other external stakeholders are interested in, but when we do bring UDI to the table these are the kinds of benefits we think can accrue.

Just so you know where we're coming from, Congress felt the same way and so they gave FDA the mandate to develop this unique device identification system in the FDA Amendments Act or FDAAA of 2007. So we have been working to implement this legislation. We have a proposed rule, which we expect will publish in June of this year and then it will go through the rest of the normal regulatory process that I can describe if anyone is really interested.

How is this going to work? In essence, every device will have a unique device identifier on it. It will be built according to standards that meet this particular ISO standard. Manufacturers will create a device identifier and a production identifier for each of their products, so that will tell us both, what the product is and the particular instance of this product. So if it's a lot controlled product it will have a lot number. If it's a serialized product it will have a serial number in it, but all of that information will be on the label or on the device itself in a human readable and in some form of auto ID, so barcodes, RFID, ... communication. We're not going to dictate the kind of technology that's going to be used, but we do expect that it will be on every device.

I think I touched on all of this right now. Just so we can see an example: The two barcodes that you see in the lower left-hand corner, the top barcode that starts with the (01) and then the bottom barcode with the (17) and (10), the top one is the device identifier and the bottom one is the production identifier. So if you were to look up in the top barcode, the 14 digits associated with this product, you would find it's one of these products. You would find some information about it. The bottom barcode is the lot number and expiration date of that product. If it was a serialized product it would have the serial number on it and those kinds of things.

We are also developing—and Terrie is here to talk to it if you have any questions—the UDI database. So for each one of those device identifiers this is the kind of information that we would expect to find in the database. All of this information will be submitted by the device manufacturer before they put the product

on the market. All of this information, and possibly other information, will be made available to the public to use. We can imagine that there is a lot of different kinds of data that could be put into the database and made available to users. One was brought up earlier today. Remind me what that was.

W
It was the interface specification—

Jay Crowley – FDA – Senior Advisor
Yes. Thank you. So we can imagine that there are a number of uses for the data in this database. This is the initial set of data that we're working with in our regulatory process. Importantly, in there is the global medical device nomenclature term, so this is the standardized term that would be used to identify the device at a generic level. So the UDI, along with the GMDN gives us that range, if you will, that continuum of identification that I talked about initially. This is basically the database will be publicly available. The manufacturer will submit data to it. Again, we will make all of that information available, and possibly other information, to users. That's the end of my presentation.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Next we'll turn to Terrie.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
I'm really his backup, but I do want to add that we at FDA, UDI is part of an overall informatics strategy that we have. We are tied to the HL-7 world through the submission of this UDI data will be through an HL-7 message structured product labeling, which, in an overall strategy for the Center for Devices, will also be linked to the HL-7 message individual case state to report, which we now use. Manufacturers submit to us their adverse event reporting data, so we look to have the UDI data connected with those two HL-7 messages. We're also tied with a lot of vocabularies, so we are a consumer and encourager of the standards that have been talked about today. We'll just take a subset of those for the various public health needs that we're discussing.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Next, we'll hear from Betsy Humphreys.

Betsy Humphreys – National Library of Medicine – Deputy Director
Thank you. I'm Betsy Humphreys. I'm the Deputy Director of the National Library of Medicine and in the interest of full disclosure, because some of this may come up, the National Library of Medicine is the developer of RxNorm. It is also the provider of DailyMed, which disseminates structured product labels for medications that are submitted to the FDA. We are a major supporter of LOINC. We are the U.S. member of the IHTSDO, which is the owner of SNOMED. The IHTSDO is currently in negotiations with the GMDN agency, because although SNOMED has a limited device nomenclature it's at a fairly high level and with a lot of encouragement from me and many others they decided that they were not going to develop yet another detailed device nomenclature and have been in negotiations with the GMDN agency. NLM also has longstanding arrangements with ... in terms of them supplying us the UMDNF for the NLM Metathesaurus and so we are connected to everyone here in various ways.

In our testimony, we focused on this end related to this panel, the terminology and the device nomenclature. We obviously might have invoked other experts from NLM, who have been heavily involved with telemedicine and could have discussed many of the other topics that were said previously. But we believe very strongly at NLM, along with many others, that we really need two things that will help us very much. It's that any device that puts out electronic information that, in the end, is going to go into an electronic health record should, in fact, standardize the data right up front when it comes out. I think we all have to deal with legacy systems. We have the 500 mappings of all of the whatevers, but I do really think that—I had a boss, an early mentor of mine, who said, "The future is longer than the past." I still believe that. Even though I suspect people are running out of that faith, but I do really think that we need to come up with some of the standardization and we need to build it into these devices that are coming out with this and not have subsequent mappings to whatever, to LOINC to whatever. I mean we could just put it out that way to begin with and I think that would be a good thing.

The other thing, of course, now we get to the UDI. We can not only output the information about the result of the test or the result of whatever the measurement, but we could also output in electronic form the device that produced it, so we would be all connected to this. We're very enthused about the UDI database. This gets us to one of our—or when it's implemented would get us to something that we think is very, very important, eventually getting to something that is similar to the structured product label database with much more information. I love the idea about all of the interface specs would be part of this database. I think we really need this and I think the FDA is learning from past mistakes of all of us that we should have this be a publicly available database. We're not in the same sad state that we are with the NDCs, which are now being cleaned up, but it would be nice not to have this problem, which is that essentially we have no publicly available database that tells us what all of these things are. So we're very enthused about getting to the point where anyone, any manufacturer or any healthcare facility, any person at home could, in essence, look at this thing and put that number in and actually find out what it is they're looking at and what the issues and so forth are with it. I think this will be hugely important for patient safety going forward and recalls and so forth. I think this is all very doable.

We have been talking about this issue of device nomenclature in various FACA Committees, including the National Committee for Vital and Health Statistics. I personally have been in hearings about this it's got to be for ten years, so I actually feel that the combination of moving forward on the UDI rule and what could also be happening with rules for the next phases here, then let's settle this. I mean let's pick one and go forward with it as far as I'm concerned and then let's have a transition strategy that connects to others that may be in use so that we can move forward on this issue. Thank you.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Next, we'll turn to Janet Trunzo.

Janet Trunzo – AdvaMed – Executive Vice President, Technology & Regulatory Affairs
Thank you. I have a presentation. It's really about a ten-minute presentation, but I think I only have five minutes, so I'm going to condense it. I am with the Advanced Medical Technology Association based here in Washington, D.C. We represent medical device manufacturers and the reason why I'm giving a presentation about nomenclature is that I'm the industry representative on the board of trustees for the Global Medical Device Nomenclature Agency and also representing the industry from the GHCF members, the Global Harmonization Taskforce members. So this is why I know a little bit about the GMDN system. Prior to being on their board of trustees, I participated in their policy group activities for many years preceding that.

So I don't think I need to tell you about the role or nomenclature. I think you understand from the previous comments about how the nomenclature fits into the UDI. From the perspective of the Global Harmonization Taskforce, our goal was always to have a single nomenclature for the harmonized regulatory model that was developed by the GHTF and the industry and the regulators supported this single nomenclature system, which in fact, was the global medical device nomenclature, the GMDN system. Right now, the users of the GMDN system are regulators and competent authorities and manufacturers, distributors, the CAHPS out there and ... bodies.

The Agency itself actually was created in 1991, initially initiated by the European Commission. But it was then incorporated into a non-profit agency in 2004 and in 2009, based on feedback from the GHTF the governance structure was modified. The way it was modified to become more of an international organization, the board of trustees was expanded so that we had representatives from all of the regions of the world. We have from China, Singapore, Australia, Europe and the U.S. There is the management, which I don't need to go into. The system itself is based on ISO 15225 and it's a system of internationally recognized coded descriptors that are used to link to identified medical devices. The database itself is a hierarchical system. It consists of almost 2,000 collective terms, which are based on device attributes, but then when you drill down and get more granularity into the database you have the preferred terms. There are nearly 20,000 preferred terms right now; a good portion of those, nearly 40% of those, are in vitro diagnostics, so this database has really increased over the last couple of years.

The preferred terms include the numerical code, the name of the term and the definition. The definitions themselves are quite detailed. They are intended to describe in very clear terms what that term name means and then the category. The category is important because when you go into the database it's important to be able to search by category, so search mechanisms are very important to understand the device attributes to be able to search by certain materials or search by whether the devices are sterile or non-sterile, electromedical or mechanical. So these are a very important way in which these terms are described and linked within the database. So there are various levels, beginning with the category, the device category, the generic device group, all of the way down to the device type. Then some of the search categories can go by the product category, the clinical specialty, the degree of device invasiveness, the device use, whether it's single use or multiple use, the material within the device and whether the device is sterile or non-sterile.

The other important feature about the GMDN at this point in time is although the database itself and the reference is in English, it has been translated into other languages, including Chinese Mandarin, Japanese, Russian. Then the EU took on a very extensive translation activity to translate into 20 different languages in the EU and that is very important because the database had to accommodate all of these translations and that project is nearly complete. So the support for the GMDN at this point is by the regulators and the industry of the Global Harmonization Taskforce. The goal is to have a globally accepted and sustainable nomenclature system for the future. Thank you. I made it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you, Janet, very much. Next, we'll turn to Jim Keller.

James Keller – ECRI Institute – VP, Health Technology Evaluation and Safety
Thank you very much, everyone. I guess I have the honor of being the last one of a long day, so good afternoon again. I'm Jim Keller. I'm Vice-President for Health Technology Evaluation and Safety from ECRI Institute. I'm also the President Elect of the American College of Clinical Engineering, although today my comments are on behalf of ECRI Institute. ECRI Institute is a non-profit, health technology, patient safety and research organization that is dedicated to bringing the discipline of applied scientific research to discover which medical procedures, devices, drugs and processes are best for enabling improved patient care. We appreciate having the opportunity to provide our perspectives in the UDI portion of today's meeting.

ECRI Institute has a tremendous amount of experience with medical technology. Next month we will be publishing the 40th anniversary issue of our *Health Devices Journal*. *Health Devices* is known for its comparative evaluation of medical devices. Our evaluations are often compared to those that are published in *Consumer Reports*. Recent health devices evaluations have begun to assess the interoperability related performance and features of medical devices. Our *Health Devices Journal* also includes guidance articles on a wide range of health technology planning, management, use and safety topics. We are currently developing what we're calling an interoperability resource center on number section of our *Health Devices* system Web site with a variety of tools and information intended to help healthcare organizations better plan for and manage interoperability. The *Health Devices Journal* has recently received some national attention for its article on our top-ten list of health technology hazards. Item five on our list, which covers data loss, system incompatibilities and other health IT complications, is directly related to the topic of today's meeting. I didn't remember to provide a copy of that article for the committee, but I'll provide that, Judy, afterwards.

A major part of ECRI Institute's mission over the years has been to create and maintain the Universal Medical Device Nomenclature System or UMDNS. UMDNS is now over 40 years old. Our UMDNS efforts also support our work for international organizations like the World Health Organization, for which we at ECRI Institute are a collaborating center for patient safety, risk management and healthcare technology. We license UMDNS free of charge to regulatory agencies, hospitals and health systems, manufacturers and distributors worldwide. Our nomenclature is, by far, the most used medical device nomenclature system on the ground in the U.S. healthcare system. It's been honed over the decades to be useful in practice, not just in theory. UMDNS is relied on by thousands of hospitals to support procurement, asset management, hazard and recall tracking, other patient safety purposes, indexing of

literature, spend analysis and quality improvement and systems level benchmarking. Currently there are more than 2,300 licensee organizations in more than 100 countries for UMDNS. One license agreement can represent individual users or an entire hospital system. For example, the U.S. Veteran's Health Administration recently signed a VA-wide license for all of its facilities.

Applications utilizing UMDNS had been developed by group purchasing organizations like Premier and by the Department of Defense for its defense medical logistics standards support or DMLSS system. UMDNS is also being incorporated into the Veteran's Health Administration's asset management system. ECRI Institute has recently begun to work with most of the capital medical equipment maintenance management systems, also known as our system vendors and those are known as CMMS products. They're being used or the UMDNS is being used to integrate into their applications. One of the functions enabled by the CMMS vendors is an automated lookup of their customers' inventories matched against UMDNS; that is the terms in UMDNS; to help identify product recalls or product recalls that are affected in a hospital's inventory.

From an informatics perspective, UMDNS is an ISO designated standard taxonomy and coding system and has been in a unified medical language system for nearly 20 years. It was recommended by the Institute of Medicine Committee on data standards for patient safety. ECRI utilizes UMDNS as a central organizing concept for all of our device related information products and databases, including our many patient safety applications. As a contractor to the Agency for Healthcare Research and Quality, we use UMDNS to encode device related concepts in a national guideline clearinghouse and the national qualities measures clearinghouse.

UMDNS has had a significant growth in the healthcare IT area. There are over 560 preferred terms within the UMDNS system that are tagged with the healthcare information technology specialty attribute. These cover a range of clinical devices, like work stations, transmit or receiver systems, computer aided detection systems, monitors and various types of health IT systems. Internationally, UMDNS is used by manufacturers for product registration by ministries of health for many purposes, by WHO and its tool for resource allocation, in developing countries and also in Asia as the foundation for the Asian Medical Device Nomenclature System.

In wrapping up, ECRI believes that with so many healthcare organizations and other stakeholders relying on UMDNS to maintain the accuracy and consistency of device terminology within their organizations across systems and beyond it's critical that UMDNS be an integral part of future technology related standards, like UDI. Otherwise, healthcare organizations will take years to adapt their various databases to other conventions at an extreme cost in dollars and patient safety. Thank you very much for your time.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. I think, Chris, your card was up first and then Nancy and then I'll go to the phone.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
My name is Chris Chute. I'm still from Mayo Clinic, but I'm remarkably uninformed about device nomenclatures, which gives me the opportunity to play the fool, I guess. Two obvious questions arise from this presentation. They clearly center around to what degree are UMDNS and GMDN, if I got the abbreviations correct, correlated, interoperable, connected, mapped, I mean whatever terminology we want to use. Then the secondary question is what are the intellectual property right restrictions or availability if you want to think of it in the more positive context of both of these systems.

M
I want to direct this question first to Betsy, who I think has a great way of expressing how the different classification systems relate.

Betsy Humphreys – National Library of Medicine – Deputy Director
Within the last, I would say, year or 18 months, the National Library of Medicine looked at both of these systems and did sort of a high level of comparison of them. This was not a complete mapping by any means. It was just taking a look at them and looking at their characteristics and so forth. We were

favorably impressed by both systems, but I do have to say that in many areas they do not organize the categories of devices in the same way. So my favorite comparison is that it's like we could either divide people up by the color of their eyes or the size of their feet and when you try to map that it's not that easy. That's too much of an expression, but I think that the categorization of the devices is different. I suspect when you get down to the actual, more granular terms and you get through the differences in nomenclature, different approaches to naming the items, you would find a tremendous amount of overlap. But I had to say that when we looked at this from our perspective mapping between the two of them will be a job if anyone decides to undertake it.

M
If it makes sense to do that for ... description.

Betsy Humphreys – National Library of Medicine – Deputy Director
Yes.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
What about the IP issues on both of them?

James Keller – ECRI Institute – VP, Health Technology Evaluation and Safety
I'll speak to the ECRI. ECRI Institute is the owner of the Universal Medical Device Nomenclature System or UMDNS, which, as I stated, we license for free to basically any organization that chooses to use it. So a very common application for UMDNS would be for a hospital to use the naming convention in their medical device inventory to make sure that they're calling the defibrillator the same thing throughout their institution or a hospital system is calling defibrillators the same thing across the entire system. Then that would be relied heavily upon, for example, to identify recalled items in a consistent manner across the system. Even a better example would be a safety notice that comes out generically about defibrillators and the hospital could flag all defibrillators in its inventory based on how they're calling that using the UMDNS system. We tag all of those items to our publications.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Free is good. To what extent does your license permit derivative work or explicit extension?

James Keller – ECRI Institute – VP, Health Technology Evaluation and Safety
I guess I'm not sure of the answer to that question. Do you have an example of what you would think that might be?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Well, certain organizations located in the Midwest that will remain nameless—referring to Mayo, of course—have a very detailed notion about device subtypes, derivatives and the like and it's improbable that any classification that serves, if you will, the general use case would be satisfactory or sufficient for specific, particularly research use cases—

James Keller – ECRI Institute – VP, Health Technology Evaluation and Safety
Yes, so there's—

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
And invariably they need to be extended.

James Keller – ECRI Institute – VP, Health Technology Evaluation and Safety
Two ways that would be handled: One is if a term doesn't exist that would meet your needs; that is often requested by the users of UMDNS. We turn those around quite quickly. Or you can use that UMDNS system as a base for the research that you're referring to and essentially expand it to meet your specific needs. That happens all of the time within the inventories that are being used throughout the world using UMDNS, where hospitals may choose to come up with a term that fits their internal workings, but isn't applicable outside of their walls and so they'll use the structure of UMDNS to help keep a standard process for naming things within their institution.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
What about intellectual property on GMDN?

Janet Trunzo – AdvaMed – Executive Vice President, Technology & Regulatory Affairs
The GMDN agency, which is a non-profit agency incorporated in the U.K. owns the intellectual property of the GMDN system. The GMDN system is developed in such a way that it has much use, can be used quite well by regulators and so the GMDN system is offered free of charge to regulators.

The idea of just looking up a term, like defibrillator, is at the very highest level and it's the example that Jim used. In the GMDN system the ability to drill down, to get more specific as to the type of defibrillator is very important and to describing a term. That's why this conglomerate of these nearly 20,000 preferred terms, which give you not only a code, which is used. But behind that code, within that database is a very detailed description of what that device actually is and the ability to search that device by a variety of categories, including, as I mentioned on my presentation, clinical specialty, the degree of invasiveness, the materials that are used in the device. So that's why it has such an application for the regulatory use.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
What about the non-regulatory use, specifically the licensing, are there fees associated with that?

Janet Trunzo – AdvaMed – Executive Vice President, Technology & Regulatory Affairs
Well, the way in which it currently is used is that manufacturers clearly are the people, the organizations that are paying the fees to license the use of a particular term. That's the way the current business model of the GMDN system is to collect license fees for manufacturers to use certain terms.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
What about other user categories?

Janet Trunzo – AdvaMed – Executive Vice President, Technology & Regulatory Affairs
Do you mean like hospitals—?

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I mean providers, researchers, investigators.

Janet Trunzo – AdvaMed – Executive Vice President, Technology & Regulatory Affairs
I don't have the breakdown of all of the user categories, but it is used by other groups other than regulators. Yes.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
With what kind of intellectual property restrictions? Specifically, do they have to license it and is there money involved?

Janet Trunzo – AdvaMed – Executive Vice President, Technology & Regulatory Affairs
They license it and yes. There is a licensing agreement, which is established. I can't really speak to the payment or how much is charged for these organizations to use it, because I don't have that data with me.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think Nancy was next.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I have three questions that are slightly different ones, so I'll start out with the general one first. What relationship do these taxonomy classifications have to the work done at GS1 related to trying to develop international device identifiers or medical/surg equipment? Can anybody answer that?

Terrie Reed – FDA/CDRH – Associate Director for Informatics

I'll have Jay answer that.

Jay Crowley – FDA – Senior Advisor
So, GS1 is the same group in the U.S. that does UPC codes, so the Uniform Code used to be the Uniform Code Council. GS1 is one of the standards that we have identified in my presentation that would probably be used for unique device identification. So GS1 helps manufacturers create the unique device identifier. It's at that granular level. GS1 does not currently have a device nomenclature in place, so they have a category that is medical device and that's it. Full stop. So they're not really in the business of nomenclature so much as they are in the business of very specific device identification.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Okay. Let me follow on then, because one of the critical things on any of these would be what is, I call it, the metadata or what is the descriptor data about this device? Because I think one of the things we want to be looking at is; and I know that we've talked; DoD and VA have talked with the FDA about getting together on a project to help; and I think it's out there; on what is the data that you need to ask manufacturers to send in about your devices. Because, as you look at trying to enter an implantable device in a patient and that eventually goes in the record, you want to be able to then automatically be able to find out if there's a recall and automatically pull that patient's record up. On my wounded warriors, I would love to have implantable device summary lists. I would love to have a durable, medical equipment list because what happens if there's a next tsunami or the next Hurricane Katrina and that patient has artificial limbs and other kinds of devices to replace. I think that is one of the questions I have on is any one of these current nomenclatures working on that, because I also feel that; and we'll come to the third question, okay? Go ahead on that.

James Keller – ECRI Institute – VP, Health Technology Evaluation and Safety
Can I address two things? First off, about the GS1: We at ECRI Institute do not have a current mapping to GS1, so I'll—

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Why not?

James Keller – ECRI Institute – VP, Health Technology Evaluation and Safety
It's not something that we're not working towards, but there's not a current mapping there. Then on the second point that you were bringing up, ECRI Institute is developing a tool that we're calling a models database, which is an extension to what actually I referred to with our work with the CMMS vendors where we're integrating our information into the CMMS systems. The models database will be linked up to a tool that we're developing to do automatic matching of products in our models database, which are linked up to also the UMDNS term to tell the DoD, for example, that you have the following items in your inventory that have been recalled based on a current recall. So that's a work in progress at ECRI Institute. It's currently actively going on.

Jay Crowley – FDA – Senior Advisor
Can I respond to that before we go too much further? You asked a couple of questions and I just think I want to tease them apart a little bit. The first was about data associated with the specific device, the metadata. That's what the UDI database is going to do and Betsy talked to that as well. I mean that's really where the power of UDI comes from. Yes, it's the same way when you go to your grocery store or to Wal-Mart and you scan the code. The code is an unintelligent number. It means nothing.

What's interesting and useful is the data behind it. That's exactly what the UDI database is intended to do. We've talked about data elements and what data elements should be there. I think this is an evolving world, but one that's very interesting. There are flags that we have, whether it's an implanted device or it's a durable medical device. I mean those are flags that can be made part of the UDI database, such that when you scan the product or you look up that product you could have whatever information it is that you were interested in.

There was something else I wanted to say, but now I've lost it, so I'll come back to it.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Just one other question: I think the third thing is I think DoD is a case where we're taking care of U.S. constituents, but we are buying around the world. We have American citizens working for us in Europe and in Japan and we buy drugs and medical devices. If we can't get thread or surgical thread we will get it from the Japanese manufacturers or those that are certified. That's where this unique identifier number gets very critical. Do I have something comparable that gives the same quality of care that will give the same outcome? I guess I would just like to say are there other efforts that you're aware of to work these nomenclatures on an international basis or is there any way that the Library of Medicine is helping to do anything on that?

James Keller – ECRI Institute – VP, Health Technology Evaluation and Safety
From a UDI perspective, we didn't get into it much, but Janet talked on the Global Harmonization Taskforce, so we've actually been working to develop a global approach to UDIs so what whether you get the product from Japan or Germany or China or whatever it is there is a UDI, which is likely the same globally. So you would be able to find information on it from wherever. Then the metadata associated with it would then be the same. We didn't talk a lot about the UDI database, but I think you touched on wanting to find substitute products and things like this. This is one of the purposes of the database and building the nomenclature into is that you could search for suture, whatever and find all of the products that are available that fall within that classification, that nomenclature term. I don't know if someone else wants to—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. I'm going to turn Chris Chute next.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
I guess I'm back on my IP theme, but I guess these are related to the FDA. I'm curious about two things. One, I'm aware of work going on on ISO TC215 and the international community for a family of interrelated suites that FDA is deeply involved with that includes, among other things, universal identifiers for drug products, patient safety reports and I believe device identifier is part of that suite. However, one of the principles that has been adopted by that is that, frankly, fallout of the MedDRA fiasco, as we call it in the terminology world, where identifiers that have intellectual property restrictions are now, I think, widely regarded by the international community as not appropriate for use as international identifiers. Yet, when I hear the description of the UDI being based on the GMDN, unless I'm misunderstanding things, we may be at risk for the same kind of syndrome from what I just heard and similarly, it seems disconnected from the work that's going on in ISO TC215, again, unless I'm misinformed. As I said at the beginning, I am remarkably uninformed about this, so I am playing the fool.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Anyone want to start?

Betsy Humphreys – National Library of Medicine – Deputy Director
Well, I can just say that the UDI, the identification of the device, is obviously one set of numbers and it's down at two very specific levels. The GMDN, as is going to be proposed, I assume, in this proposed rule is at the higher level, which is more standard nomenclature for the device. So we could regard this as quite similar to the difference between the NDC and the RxNorm for the same drug. That said, that doesn't address your issue, because my assumption would be that if we're going to have a publicly available database then everything in the database has got to be publicly available, right?

W
Yes.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Yes.

Betsy Humphreys – National Library of Medicine – Deputy Director

So I think that the assumption is that there will be a shift in IP arrangements on GMDN and there is some work along those lines, but the others in the room know more about that than I do.

Janet Trunzo – AdvaMed – Executive Vice President, Technology & Regulatory Affairs
Our ultimate goal from the Global Harmonization Taskforce—I just want to say how all of these things are linked. There has been a slew of activity over the last year or so. The GHTF has strived for harmonization with the UDI and with the nomenclature system and the support that the GHTF gave to them for the use of the GMDN system. The ultimate goal is to make it freely accessible to anybody who needs to use it. That's the ultimate goal. One of the reasons why the GHTF was very forceful in ensuring that the agency itself became more of an international board of trustees to take into consideration the international needs was to look at mechanisms to make it more freely accessible. One of the things that was brought up earlier was that the GMDN agency and the IHTSCO are in talks right now to work towards a common goal.

At the same time, you have the UDI, as Jay mentioned, where you have the GHTF wanting to be proactive in harmonization of unique device identifiers. They work together. It's important to have the unique device identifier so you drill down into knowing exactly the make and model and who made the device. The nomenclature system alone will not give you that information, but the nomenclature—the naming system—is so part and parcel to the UDI. So the GHTF established an ad hoc working group in order to move towards a harmonized approach to UDI so that the UDI database will have the similar data elements that are necessary for device identification. That's the other activity that's ongoing so that other jurisdictions around the world, when they adopt their UDI system, will have the same information that the FDA will have in its system. That's the other ultimate goal, so all of these things are kind of coming to a crescendo I would say in the next six months or so.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. I'm going to take the prerogative to ask a couple of questions myself and then I'll turn to the phone and see if our members on the phone have further questions. I think, Jay and Terrie, these are probably both for you, but I'm thinking back to those providers, both hospitals and eligible professionals, who may apply for the meaningful use incentives and who are implementing EHR technology that have needs for device identification potentially in their EHRs. I think a lot of what we've heard here or some of what we've heard here is that there is certainly widespread use, particularly on the hospital side. Where many of the hospital meaningful users have implemented the UMDNS inside their hospital systems and are using this for exactly the purposes that I think, Jay, you laid out for correctly identifying recalled implanted devices, things of that nature.

Yet, I think we also heard that there is less, perhaps because of the fee, the licensing fee, that there is less, if any use of the GMDN by the same meaningful users today. So I'm wondering about this sort of conversion, if the UDI is to include the GMDN, but perhaps not the UMDNS as part of its database that's going to be publicly available. How do you think the conversion can be managed for these meaningful users in the time frame of meaningful use? Perhaps I'll just ask my follow-on question right now on that one, which is do you think it's possible just to have the UMDNS as an additional attribute in this database that you're going to make available?

Jay Crowley – FDA – Senior Advisor
Well, the two questions seem very related, so I'm glad you asked them both. I think we do need; and Betsy mentioned this before; a transition strategy, whether that's a short-term and or long-term is something we can debate. There are other nomenclatures that are used too. UNSPSC is used by many organizations, including Mayo, first in analytics and a number of other functions. So we have some issues that I think we need to deal with. There are systems that are in place. There are homegrown nomenclatures that are used by various institutions. So I think there are a number of issues that we need to deal with in terms of transition, what that looks like. Could we add any number of nomenclature attributes to the database? I'm sure in theory we could. I'm not sure how happy our attorneys will be, but we'll struggle with that one later on. So yes, I think we do need some sort of transition strategy. I mean if this is the path that we are going to be on then we do need to make sure that people are going to be able

to use it in the near-term and the long-term. We're open to these discussions. I do think they do need to happen.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
do have another question also, focused from the perspective of ... Nancy, did you have a follow-up to that one?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I think it's related to the timing. When are these going to be available? That's the question. Will they impact meaningful use stage two or are they really stage three, your databases, or maybe longer?

Jay Crowley – FDA – Senior Advisor
Well, welcome to the U.S. regulatory process. We're probably a good year from implementation, beginning implementation. Full implementation is years out, but I mean we are beginning, so I don't know how to answer that. I mean most class three products will be like, hopefully, fully implemented within two years. Keep our fingers crossed. So that's all of your implants or most of your implants and those kinds of products. We have a fairly long timeline. We have a lot of device manufacturers, big, small, tiny, huge, so we have a fairly long timeline for full implementation of EDI. Having said that, I think we'll see most devices implemented in the next two to four years with some stragglers along the road.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
My next question is also from the perspective of the meaningful users, again, those who may be applying for the incentives. I'm thinking about it particularly for the hospital incentives program, but it may apply also to the eligible professionals program. I think something that we've discussed previously is that a large number of the hospital meaningful users expect to be manufacturers of some kind of MDDS under the new rule. So I wanted to focus on the requirements that they would have for the structured product label and submitting to the UDI from their perspective. So I guess I'm just wondering if you've thought through how the structured product labels and the UDI would be generated for the medical device data systems for which, actually, the meaningful user becomes the manufacturer? Are there any particular characteristics that the implementers of the EHR technology need to know about to actually work that into the meaningful use time frame?

Jay Crowley – FDA – Senior Advisor
Terrie, do you want to take that one?

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Well, MDDS is class one consent. We have a risk-based product so, as Jay said, this timeline is—actually, I think our timeline is like 2017—

Jay Crowley – FDA – Senior Advisor
For class one.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
For class one devices.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. So that clarifies it a lot for me because actually, in fact, the timeline by which the meaningful users would have to generate the SPLs for their interfaces basically that they code would be longer than meaningful use, but it would still be, I mean, I guess the same question. It's just a matter of timing, right?

Terrie Reed – FDA/CDRH – Associate Director for Informatics
We haven't really talked about meaningful use in terms of—I don't know that we specifically requested that UDI be part of the EHR for meaningful use—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Yes. Actually, I think that was part of one of the presentations, part of the written testimony. That's why I wanted to focus in on that. So if that's going to be considered then I think the potential, since I think the MDDS would have to go into the database just like any other device, right?

Jay Crowley – FDA – Senior Advisor
Right. I mean from that perspective it would be no different than an IV catheter or anything else like that. The manufacturer of that product would be responsible for assigning the UDI and submitting the data to the database. By that point, hopefully, we'll have all of the kinks worked out so it will be pretty straightforward for them.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
But I guess just from the perspective again of those implementers of the EHR who will be applying for the incentives, in some cases that they may consider to be just a configuration of a vendor supplied interface. They, in fact, make them a manufacturer and, therefore, responsible for the SPL, right?

Janet Trunzo – AdvaMed – Executive Vice President, Technology & Regulatory Affairs
I do want to say, because we have on the device side many small manufacturers, so they wouldn't necessarily have to understand HL-7 SPL. One of the big things that we will be providing is a portal for those small manufacturers, so it would just be a matter of data entry or we're going to provide the most usable interface we can to meet the needs of our small manufacturers. So that would be that category as well.

James Keller – ECRI Institute – VP, Health Technology Evaluation and Safety
Jamie, can I make a comment on MDDS?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. Please.

James Keller – ECRI Institute – VP, Health Technology Evaluation and Safety
One of the notes that I made related to one of the questions was, I think it was on the impact of MDDS on device integration and interoperability. My perspective on MDDS for hospitals is that it will slow down their interoperability because they're going to have to implement some of these quality system, regulation types of processes that they've never had in place before. So it's going to kind of put the brakes on a lot of hospitals and how they integrate or interoperate medical devices with one another and into the EHR. I think that we don't know how significant that's going to be because there isn't a really good inventorying of all of those types of networks and systems that are taking place or being made by hospitals. The FDA, actually in collaboration with ECRI Institute, is looking into that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. Thank you very much. Let me check for our committee members on the phone, if you're still with us, if you're hanging on after a long day there on the phone, if you have any questions for this panel.

Don Bechtel – Siemens Medical – IT Architect, Standards & Regulatory Mgr.
No questions for me.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
No questions for me.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Jay, you wanted to comment?

Jay Crowley – FDA – Senior Advisor
I just wanted to make the committee aware: This whole notion of UDIs and documentation and electronic health records and other clinical information systems is something that we're very, very interested in. To that end, this fall we anticipate having a public meeting on this issue, not to ... what's going on here at ONC, but simply to have a larger conversation about these issues and what can be done. What are the

incentives and what are the barriers? So this is something that's, I think, critical to what we see as the success of UDI, so it's something that we really want to try to be on the leading edge of.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, if there are no other questions from the committee members then I think we're at a wrap for this panel. Thank you very much; a very illuminating discussion. I really appreciate both, the presentations and the discussion.

Thank you. I'd like to take just a minute at the close of the meeting, before we go to public comment, to reflect on just a few of the themes that we heard from today. Just from my notes; I do have several pages of notes, but I'll just try to skip through a couple of the things and call them themes. One thing I think we heard was that consumers and patients, which are different, or who are different, need interoperability to be made cheap and easy for them. That's both, to drive compliance with the care plans and to improve outcomes for home monitoring in particular.

We also heard that perhaps the biggest problem from their perspective is last mile connectivity and setup in the remote environment. We heard several stories about different approaches to managing that setup and connectivity for in-home setup, but there was no real consensus I think on how that works consistently. We also heard that middleware and data intermediaries are necessary for the foreseeable future.

We heard actually quite a lot from providers. We heard talk about some of the problems, as well as some of the benefits from a provider perspective. I think we heard that the providers who may seek the meaningful use incentives see many problems. Certainly, they see a set of problems with updating device security without assurance about the safety of those updates from the device manufacturers. We also heard that there are problems with non-standard vocabularies across the different devices that are in use. There are also a different set of problems in terms of there being no standard in EHR technology to receive and hold the device source data. Other problems with payment and incentives perhaps are out of scope for this committee, but certainly we've heard that quite a few times; that there may be no reimbursement in many cases for the use of the devices in these cases.

There are problems also not getting all of the data; that they only get a subset. The providers frequently get just a subset of the device data. They want all of the data all of the time essentially so that they can do their own filtering and not have it sort of pre-filtered, if you will. We also heard that assuring the remote patient identification is correct is perhaps the top problem for remote devices from a provider perspective. But there are also providers that see a whole lot of value here and certainly, we heard a lot, particularly at the beginning of the day about the partnership with care teams that is strengthened through the use of devices, particularly in remote settings. We heard a lot of evidence about great improvement in outcomes, lower cost, lower admission and readmission rates, so clearly, very high benefits.

We also heard, I think very interestingly, from the EHR vendors that for whatever combination of reasons, they're not able or not focused on establishing true what I would call end-to-end interoperability with all of the devices. But they're really focused on interoperability from intermediary data sources that then send the data into the EHR using standards, such as the IHE or continuous standard. That's the current focus from the EHR vendor community, but there are certainly a few—I would say, it sounded like a relatively few, consumer devices that do have that end-to-end interoperability certification from ... where sort of the last mile into the EHR, if you will, is the same as the IHE specification. But that's perhaps a very small minority of the devices. Then we also heard some concerns expressed about essentially vendor run certification programs versus those with certification run by independent, third-party organizations, like the EHR program, the way that is run.

Those are just some of the few themes. I'll just pick out a few things from the day here. It's very hard to summarize a full day sort of on the spot, but let me just ask for input from the workgroup here, from the committee and any further input from our panelists before we turn it over to public comment.

W

I think we heard there are maybe two or three or maybe three or four different problems that were all addressed today. I think the last one talked strictly about the taxonomy nomenclature of naming the devices. We talked about what data should a device send. There was security of the devices. Then I still think there is an issue of the metadata, what is going to be the standard kind of data that we want to ask come from devices into records and whether it's the naming metadata or whether it's the patient information data. I don't think we solved all of those today. I don't think we've heard enough about those. I mean I think those are going to take some further issues on—

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
We did hear something on each of those, right?

W
We did hear something and I want to definitely commend. I know how long this has taken to put this whole set of questions together and we were talking about this even in November. So I definitely wanted to commend you and everybody else, who was able to participate today. We have addressed all of those areas. I can see that it leaves the challenges. There is still lots of work.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Good.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes. I think we learned, as always, that nothing is as easy as it appears until you try to make it easy to understand. But in particular, we got clearly conflicting advice on stage two of meaningful use. To a certain extent, I felt a great deal of sympathy with both sides of that equation, but unfortunately, I think that's one of those questions that you have to answer.

On the one hand, there is an argument that some sort of meaningful use requirement that supports home health organizations using remote monitoring seemed—there was a clear statement from one speaker and it sounds very good to me. There were strong arguments for why there is a larger impact for those patients and for other patients. What is not clear to me is what the levers are that could be used in order to encourage that. In particular, the speaker mentioned EMRs, but I don't think those are EMRs, EHRs in the sense we use it for meaningful use. I think it's less of a standards issue than it is a "meaningful use issue."

On the other hand, whether we're talking about devices operating in the hospital that generate data that goes to an EHR or remote monitoring devices that generate data for coordination of care, we heard there's an awful lot of work to do from Tim Escher in particular. We should not plan on doing things until stage three, but I don't think if we wait until stage two to decide on stage three we'll be in any different position. So I felt a great urgency to work in that area.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Yes, I agree completely. We did hear from several of our panelists that basically, I think stage three is a workable time frame for getting things implemented, but they have to start now to get things done then.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
... not stage two, maybe stage three.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. Right. I think that's right. I think that's right. I also want to reinforce and echo what you said—and I think I went through the written testimonies before coming here today. I counted seven of them that cited—in different words sometimes, sometimes in almost exactly the same descriptions—different problems of the business model, probably most extensively by Mr. Cooper, but about the business model being a problem for actually implementing sort of end-to-end interoperability. And not so much the existence or non-existence or availability of suitable standards for that use. So I think that's going to be something for us to have further discussions on as well.

Any other comments from committee members here or on the phone? Yes, Betsy?

Betsy Humphreys – National Library of Medicine – Deputy Director
I just would like to say that when I was looking at some of the testimony and listening to this that I thought it all fascinating. This is obviously a very important area and I am hoping that the fact that we are now moving into classes of devices and are worried about the fact that they are putting out non-standard data and we are trying to bring them together, that we will not in that process create more vocabulary standards that we don't need. I really feel that if in fact some of the existing vocabulary standards that actually do report out those particular clinical values or know about that test or whatever are not perfect maybe what we ought to do is perfect them. Rather than ending up with the fact that we now have another group of people who understand they need to have standard vocabulary that that will generate four or five more standard vocabularies. I hope we can avoid that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you. Judy?

Judy Murphy – Aurora Health Care – Vice President of Applications
Just a quick comment about the meaningful use: I think the first panel where we were talking about the benefits and the value proposition of doing these kinds of interfacing with the electronic health record are going to be key, because if we think about the maturation of the staged criteria, stage one was the capture. Stage three is the improved outcomes. So if we want to link ourselves or this work somehow with stage three we really need to be focusing on how the type of interfacing and connectivity that we're talking about would change the outcome.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you very much. Now I think we're ready to turn it back. Let me just double-check. Anything on the phone from our members on the phone? Okay. Then we're ready to turn it back to Judy for public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
This is the time we'd like to invite public comment. Just a reminder, if you just say your name, your organization and there is a three-minute time limit.

Elliot Sloane – Drexel University – Professor & Director of Health Systems Engineering
Hello. Elliot Sloane again from Drexel University and speaking for IHE, the patient care device domain. I feel a little bit like a kid, who asked for a swing and went out back and found this huge Taj Mahal built. When we said device identifiers originally with patient care device communication we were talking about simply having some way of serializing, enumerating a particular device and understanding what that device was. Was it an infusion pump or a spirometer or pulse oximeter? Now we're in the larger field of all of the zoology of all of the things and I don't know how to get out of this thicket at this point.

The observation is that the clinical data we're sending we are cataloging and we have terms, as you've said. We shouldn't reinvent that. The enumeration of the devices for stage two and stage three are pretty modest is what I'm hearing everyone's general expectations are. Then we're really going to have to look at how to get product specific information into that record. Because none of us relish adding something that looks like what's on the router that we have at home and typing in for every band aide and product a 15-character, alpha-numeric code or trying to impose on everyone having the exact same scanners and adapters for all of the EMR types of systems, PHRs and the like. So we've started with a small problem – it was always a relatively small problem – and it's a huge problem now. We'd like to work with the IHE patient care device domain, the IHE community, IEEE 11073, work to come up with a modest solution that will get us through the next four or five years, a workable solution. And also look at what do we want to accomplish and capture in supplies, implants and other complex pieces of information in an affordable way that improves healthcare and reduces costs. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director

Thank you, Dr. Sloane. We do have a comment on the phone. Would you please identify yourself?

Operator
Our question comes from Robin Raiford.

Robin Raiford – Allscripts – Executive Director, Federal Affairs
Hello. It's Robin Raiford from Allscripts and I had two comments to make. One is certainly to support what Nancy Orvis said about the wounded warrior and implanted devices and how incredibly important that is before you get into exchanging any information from a piece of this whole idea of implanted devices. Maybe they're going to relay some information and maybe they aren't, but yet they play a key role in can you care for that patient.

I'd like to relay an insanity going on in my own family where my nephew, unfortunately, is paralyzed from a hospitalized infection. During that course of time of trying to get a brain tumor out they put in two devices and six weeks later when they went to discharge him to rehab things got so convoluted and what was happening is now a 30-year-old person is now paralyzed. They didn't give him a device identifier card and so now five years later the doctor in another state is saying, "Well, we can't find the number and you can't go in an MRI scanner. Then we can just take those devices out and replace them," which is a little bit crazy when they're talking about these things are implanted in his brain. So just even to identify the device and capture that in the electronic medical record; and Nancy had said what about a tsunami. Just any vacation, evacuation or anything where that person is out of town and gets a headache, you don't know if you can put them in an MRI or not.

The other thing I've been listening all day here—and I think it was kind of implied, but nobody really said it. It's interesting nobody said anything about UCOM or just a standard units of measure dictionary and just as a quick check, to even ask Judy or Liz to go into Aurora or Tennant and see how many entries you have in your units of measure dictionary. I would bet that none of them have anything close to the 595 entries that are in the units of measure. If we're going to have meaningful exchange of data are we actually going to have to tackle this, which HITSP had brought up. I think originally the HIT Standards had proposed to make UCOM the units of measure dictionary, at least for labs, if that issue at some point is going to have to be tackled or we're not going to get to where we want to go.

Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Robin. We have one more commenter.

Eileen Erinoff – ECRI Institute – Director, HTA/EPC Information Center
I'll be brief. I know it's the end of the day. My name is Eileen Erinoff. I'm with ECRI Institute and I just wanted to clarify the answer that Jim Keller gave to one of the questions that was asked when you were asking about intellectual property and UMDNS. We do reserve a whole range of numbers that individual users can use within their facility so that they can have a controlled system to track their own terms, although what we prefer is for them to first contact us to see if it's something that's already in the vocabulary or if it's something that belongs to be there. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Eileen. Another commenter? Yes.

John Zaleski – Nuvon – CTO and Vice President, Clinical Applications
In the discussion on security, especially related to networking security, as well as operating system security, one thing that I thought would be appropriate is to describe one of the benefits that certain device intermediaries can provide is that proxy for serialized connections. In other words, some intermediaries can actually provide the level of not only networking security, but operating system security to front-end certain medical devices. So from the perspective of considering the broad range of how to deal with, as an example, network updates or operating system updates to certain vulnerable devices,

just something you should be aware of is the fact that it doesn't all have to be taking the burden on the medical device. There are ways, potentially, to address this through intermediaries as well. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Charles?

Charles Parisot – GE Healthcare – Manager, Architecture and Standards
Yes. A comment, which is a little bit of a takeaway of the day, is I have been both, surprised and challenged and I believe that this is something this working group could help with. In filling the gaps between today's provider perception of the state of interoperability in bringing data inside their EHR and the promise of the standard and profiles and specifications that are coming out of IHE and PCD. Those are, as we said, quite fresh out of the press, testing, test tools; all of that is just now available.

It seems to me that one thing that we could greatly benefit from is to foster pilots in the next year or so where we can actually test the standards, their deployment, their maturity in actual provider institutions. If some of those that were on the panel here want to contact the EHR Vendor Association I sure would make an extra effort to connect this and to make sure we do this in a way that we can provide feedback in the next six months or year to this panel. Basically make sure that whatever we do for stage three, planning it in stage two is something we can confirm along the way. That would be the encouragement that I would like to give to this group is I think it is better to plan carefully things with pilots than confirming a stage three requirement in stage two and then tweaking along the way as we measure the implementation.

One last comment about the units of measures: All of this is entirely addressed in the ... terminology mapping, every device, every measurement and all of the units and the way to express them. All of this is categorized and not left to interpretation, so there is work in this area that could further help. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Thank you to the public for staying with us. Jamie, do you want to have a last word?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think, actually, John wants to have the last word.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
Since in the minutes we'll state about home care I just wanted to emphasize that devices and that for monitoring and things that are used in skilled nursing facilities, they're also used in therapy for outcomes and hospice that we don't, in the minutes, just say it's home care, because it is throughout long-term and post-acute care. I also want to emphasize a little bit what we talked about the wounded warriors. I'm a retired NAVY captain, so I know that's very important, but there are a lot of disabled people that have the same problem out there and that's a big one. They live longer now with a lot of different devices and so disabled and wounded warriors are an important group of people. Then you all know my feelings about meaningful use and outcomes that we should be including in stage two long-term, post-acute care providers in order to get outcomes across all of the spectrum of care.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, thank you, John. Thank you, everyone, for a very productive day.